



2008

# Global Health Law: Health in a Global Community

Lawrence O. Gostin

*Georgetown University Law Center, [gostin@law.georgetown.edu](mailto:gostin@law.georgetown.edu)*

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# GEORGETOWN UNIVERSITY

## O'Neill Institute for National & Global Health Law Scholarship



Research Paper No. 15  
September 2008

### Global Health Law: Health in a Global Community

in

### PUBLIC HEALTH LAW POWER, DUTY, RESTRAINT

(Revised & Expanded Second Edition 2008)

Lawrence O. Gostin

The Linda D. and Timothy J. O'Neill Professor of Global Health Law  
Georgetown Law

[gostin@law.georgetown.edu](mailto:gostin@law.georgetown.edu)

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## CHAPTER 7

# Global Health Law

*Health in a Global Community*

If we believe that men have any personal rights at all as human beings, they have an absolute right to such a measure of good health as society, and society alone is able to give them.

Aristotle

The examination of public health law has thus far focused on constitutions, statutes, regulations, and common law at the national and sub-national level, particularly in the United States. However, the determinants of health (e.g., pathogens, air, food, water, even lifestyle choices) do not originate solely within national borders. Health threats inexorably spread to neighboring countries, regions, and even continents. People's lives are profoundly affected by commerce, politics, science, and technology from all over the world. Global integration and interdependence occur "as capital, traded goods, persons, concepts, images, ideas, and values diffuse across state boundaries."<sup>1</sup> It is for this reason that law and policy need to be transnational—extending beyond sovereign nations.<sup>2</sup> There is no other way to truly ensure the public's health than through cooperation and global governance (see box 13).

This chapter searches for reasons as to why health hazards seem to change form and migrate everywhere on the earth; why extant global governance systems are frequently ineffective; and how international law can be used as a tool for improving the health of the world's population, especially the poorest and most vulnerable. This requires an understanding of the global dimensions of disease and of man's role in harming the planet; the meaning and sources of international law; and modern international regimes of high relevance to health, including infectious disease, tobacco, trade, and human rights.<sup>3</sup> Illuminating the complex and voluminous field of global health law is impossible in a single chapter,

## BOX 13

## GLOBAL GOVERNANCE FOR HEALTH

International law used to be defined as the law that governs relations between states, and undoubtedly, the rights and obligations of sovereign countries are still salient. However, global health governance is more broadly concerned with rules of conduct that influence or bind actors in activities, relations, and transactions that transcend national borders.<sup>1</sup> Thinking of global governance, however, only in terms of what governments do is unsatisfactory. Governance for health is complex and multifaceted. A broad range of stakeholders exert considerable power over events that influence health.<sup>2</sup> These stakeholders may act alone, in partnership, or in conflict; separately and together they influence the conditions in which people can be healthy or be placed at risk:<sup>3</sup>

- Intergovernmental organizations (IGOs)—see table 7
- Nongovernmental organizations (NGOs)—see table 8
- Multinational corporations—e.g., tobacco, food, energy, and technology
- Philanthropic organizations—e.g., Gates, Rockefeller, and Ford foundations and Clinton Global Initiative
- Public/private hybrids—e.g., Global Fund to Fight AIDS, TB and Malaria<sup>4</sup>
- Media outlets—e.g., CNN, BBC World, and al Jazeera

To demonstrate the power of nonstate actors, consider the influence of the Gates Foundation. With Warren Buffet's gift of \$37 billion in 2006, the foundation has the capacity to donate \$3 billion per year to improve global health equity. This single source of funding comprises nearly one-fourth of all financial assistance to developing countries, including funds provided by governments, IGOs, and private donors combined. Now consider that there are no international rules that require transparency, fairness, or accountability on the part of private foundations. International law does not usually reach private actors, even if they profoundly affect global health. Should global governance extend to nonstate entities, and if so, what innovative mechanisms could be established?

<sup>1</sup> Some scholars prefer the term *transnational law*, defined as "the law which regulates actions or events that transcend National frontiers . . . includ[ing] both . . . public and private international law." Philip C. Jessup, "Transnational Law 2," in *Storrs Lectures on Jurisprudence* (New Haven, CT: Yale University, 1956): 136. "The term 'transnational law' has been used to describe . . . the creation of law in the international context by governments, international organizations, and non-state actors." Matthias Lehmann, Comment, "A Plea for Transnational Approach to Arbitrability in Arbitral Practice," *Columbia Journal of Transnational Law*, 42 (2004): 753-81.

<sup>2</sup> For example, after Warren Buffet's gift, the Gates Foundation will donate \$3 billion per year to improve global health equity. This single source of funding will comprise nearly a fourth of all health-related donations to developing countries. Susan Okie, "Global Health—the Gates-Buffet Effect," *NEJM*, 355 (2006): 1084-88.

<sup>3</sup> Scott Burris, "Governance, Microgovernance and Health," *Temple Law Review*, 77 (2004): 335-61; Nana K. Poku and Alan Whiteside, eds., *Global Health and Governance: HIV/AIDS* (London: Palgrave Macmillan, 2004).

<sup>4</sup> As a partnership between governments, civil society, the private sector, and affected communities, the Global Fund represents an innovative approach to international health financing. The fund was created to finance a dramatic turnaround in the fight against AIDS, tuberculosis, and malaria. These diseases kill over 6 million people each year. The Global Fund, "Investing in Our Future: The Global Fund to Fight AIDS, Tuberculosis and Malaria, 2002-2006," <http://www.theglobalfund.org/en/>; see also Allyn L. Taylor, "Public-Private Partnerships for Health: The United Nations Global Fund on AIDS and Health," *John Marshall Law Review*, 35 (2002): 400-407.

TABLE 7. Major intergovernmental organizations working on health

IGO	Mission	Major Health Initiatives
United Nations	Promote respect for human rights, protect the environment, fight disease, and reduce poverty	<i>Millennium Development Goals:</i> Eradicate extreme poverty and hunger Ensure universal primary education Promote gender equality Reduce child mortality Improve maternal health Combat HIV/AIDS and other diseases Ensure environmental sustainability Develop global partnership for development
UN Specialized Agencies		
World Health Organization (WHO)	Support attainment of the highest possible level of health for all people	Framework Convention on Tobacco Control International Health Regulations Global Strategy on Diet, Physical Activity and Health
Joint UN Programme on HIV/AIDS (UNAIDS)	Coordinate global response to HIV/AIDS	Declaration of Commitment on HIV/AIDS International Partnership against AIDS in Africa World AIDS Campaign
UN International Children's Emergency Fund (UNICEF)	Serve socioeconomic and health needs of women and children	Baby-Friendly Hospital Initiative Int'l Code of Marketing for Breast Milk Substitutes
UN Women's Fund (UNIFEM)	Reduce poverty, violence, HIV/AIDS, and gender inequality	Trust Fund to Eliminate Violence against Women

TABLE 7. (continued)

IGO	Mission	Major Health Initiatives
UN Development Programme (UNDP)	Reduce poverty, preserve the environment, and strengthen democratic governance	UN Capital Development Fund
UN High Commissioner for Refugees (UNHCR)	Provide legal protection and emergency relief for refugees	Research on mental and physical health of refugees, and policies on HIV/AIDS
UN High Commissioner for Human Rights (UNHCHR)	Monitor national efforts to meet obligations under human treaties	Special rapporteur monitors and recommends policies to advance the right to health
International Labor Organization (ILO)	Promote social justice and monitor compliance with human and labor rights treaties	Safety and Health at Work and in the Environment
Food and Agriculture Organization (FAO)	Improve nutrition, agricultural productivity, and the lives of rural populations	Program on HIV/AIDS and the World of Work Codex Alimentarius Commission develops safety standards and codes of practice under the Joint FAO/WHO Food Programme
World Organization for Animal Health	Promote animal welfare and prevent the transmission of disease between animals and humans	FAO Crisis Management Centre Global Early Warning System for Animal Diseases Transmissible to Humans
World Bank Group	Provide loans, grants, and advice to low- and middle-income countries	Int'l Bank for Reconstruction and Development Int'l Development Association
World Trade Organization (WTO)	Ensure smooth and predictable global trade flows	Trade Related Intellectual Property Agreement Doha Development Agenda

NOTE: Intergovernmental organizations (IGOs) are organizations of international scope whose members are sovereign nation-states. IGOs are established by treaties, which bring the organizations under the jurisdiction of international law and grant them powers to enter into agreements with states and other organizations. Membership in IGOs, such as UN specialized agencies and the WTO, is open to all nation-states.

TABLE 8. Major nongovernmental organizations (NGOs) working on health

NGO	Mission	Focus
Health Opportunities for People Everywhere (Project HOPE)	Health education, policy research, humanitarian relief, and socioeconomic development assistance	Infectious diseases (including HIV/AIDS), women's and children's health, humanitarian assistance, etc.
International Committee of the Red Cross (ICRC)	Assistance and protection for prisoners of war and civilians affected by war	State compliance with Geneva Conventions
Doctors without Borders/Médecins sans Frontières (MSF)	Medical care to communities affected by natural disasters, conflict, epidemics, and poverty	Campaign for Access to Essential Medicines: advocates for lower drug prices in developing countries and research on neglected diseases
Family Health International (FHI)	Prevention of HIV/AIDS and improvement of access to reproductive health care in developing countries	Reproductive health and HIV/AIDS
Global Health Council	Umbrella NGO whose members work to improve global health	Infectious diseases (including HIV/AIDS), women's and children's health
Population Council	Coordination of international public health and biomedical research, and strengthening of local health care	Reproductive health and HIV/AIDS
PATH International	Advancement of health care in developing countries	Health training and education, contraceptives, injection devices, and diagnostic tools

NOTE : Nongovernmental organizations (NGOs) are private organizations not affiliated with (though often in part funded by) governments; they typically pursue social justice, development, and humanitarian activities. More than 30,000 NGOs work internationally.

but this text will serve as an introduction to the impressive literature that is emerging.<sup>4</sup>

#### GLOBALIZATION AND THE SPREAD OF INFECTIOUS DISEASE, MAN-MADE AND CONTROLLABLE

Disease amplifiers are principally man-made and therefore controllable.<sup>5</sup> Human beings congregate and travel, live in close proximity to animals, pollute the environment, and rely on overtaxed health systems. This constant cycle of congregation, consumption, and movement allows infectious diseases to mutate and spread across populations and boundaries. The global population is also vulnerable to deliberate manipulation and dispersal of pathogens. Those engaged in bioterrorism have incentives to move pathogens to places where they will have the most destructive impact. These human activities and many more have profound health consequences for people in all parts of the world, and no country can insulate itself from the effects. The world's nations are interdependent and reliant on one another for health security (see figure 25).

**Mass Congregation, Migration, and Travel.** Infectious diseases spread among populations and geographic areas as human beings congregate, migrate, and travel. Mass movement of people occurs naturally as individuals travel to urban settings in search of livelihoods and social attachments.<sup>6</sup> People may also be compelled to travel in large numbers as they flee situations of famine, violence, civil unrest, or war.<sup>7</sup> The gross unsanitary conditions in refugee camps and other mass settings are deeply troublesome from public health and humanitarian perspectives.<sup>8</sup> Overpopulation, whether through voluntary or forced migrations, places a strain on drinking water, food supplies, and sewage systems, providing a breeding ground for infectious disease.

**Human/Animal Interchange.** People do not merely congregate together but do so in close proximity to animal populations through intensive farming, meat production (farming, slaughtering, and eating animals), and exotic animal markets.<sup>9</sup> Such interactions with animals entail serious risks as novel pathogens mutate and jump species.<sup>10</sup> For example, live bird markets, traveling poultry workers, fighting cocks, and migratory birds are vectors for spreading avian influenza A (H5N1).<sup>11</sup> Farmers contribute to microbial resistance through overuse or inappropriate use of pharmaceuticals.<sup>12</sup> Animal diseases have significant economic consequences, as illustrated by outbreaks of bovine spongiform encephal-



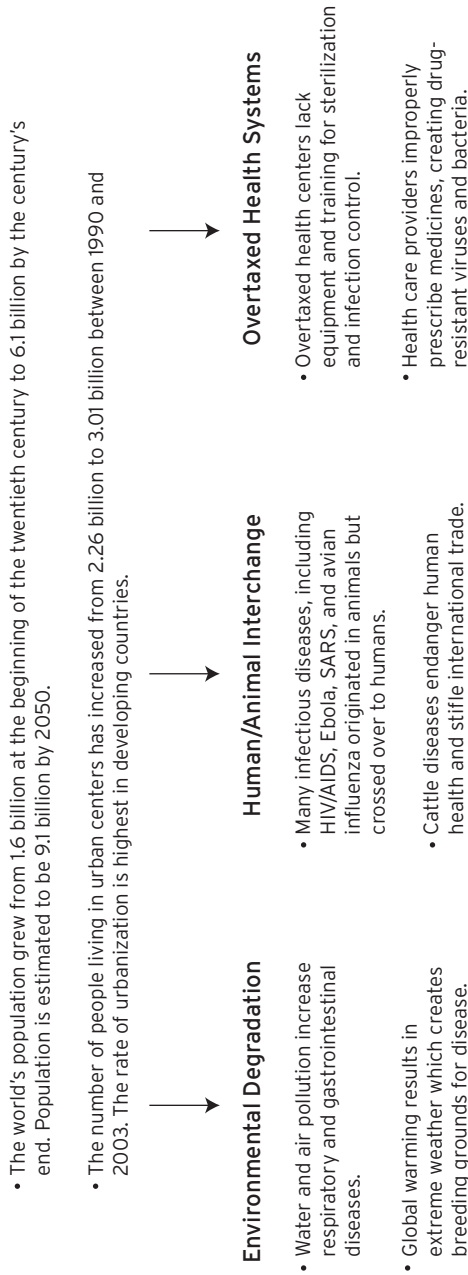


Photo 13. Health communication campaign posters: tuberculosis and tobacco. Posters encourage the public to take an active part in disease control. Courtesy of the Commonwealth Pharmaceutical Association and the World Health Organization.

opathy (BSE) and foot and mouth disease.<sup>13</sup> Animal diseases also affect human health; animals, particularly wild animals, are the source of 70 percent of all emerging infections.<sup>14</sup> These processes have transnational dimensions, as a result of thriving international markets in cattle, meat, and poultry.

**Ecosystem Degradation.** Human well-being is highly dependent on ecosystems, and ecosystems are sensitive to human activity. Ecosystem degradation in one geographic area affects other parts of the world; in this way, living systems (e.g., air, sea, forests, and soil) are interconnected, as are people and places in the world.<sup>15</sup> Ecosystem degradation has multiple adverse health effects.<sup>16</sup> For example, air and water pollution increases respiratory (e.g., asthma) and gastrointestinal (e.g., cholera and *E. coli*) diseases, as well as cancers. The emission of heat-trapping gases (e.g., carbon dioxide, methane, and nitrous oxides) contributes to global warming, which causes a number of health hazards: heat-related illnesses and deaths; infectious disease carried by insects and rodents (e.g., malaria and West Nile virus); droughts that result in famine and conflicts over

### Mass Congregation



• 75% of all deaths from infectious diseases occurred in Southeast Asia or sub-Saharan Africa.

• More than 90% of deaths from infectious disease are caused by lower respiratory diseases, HIV/AIDS, diarrhea, tuberculosis, and malaria.

Figure 2.5. The transnational spread of infectious diseases.

water resources; and natural disasters that produce floods and destruction (e.g., the Asian tsunami and Hurricane Katrina). Finally, excessive and unsustainable use of scarce resources (e.g., deforestation, strip-mining, and intensive farming or fishing) diminishes natural assets needed for healthy living.<sup>17</sup>

**Health Systems.** Health care systems themselves can contribute to poor health. The lack of sterilizing equipment, safe blood supplies, and basic infection controls in resource-poor hospitals puts both health care professionals and patients at risk for bloodborne diseases, such as HIV/AIDS and hepatitis B or C. Weak public health infrastructures can fail to detect and contain outbreaks of Ebola or SARS in their early stages, giving these diseases opportunities to spread. Lack of funding and infrastructure in turn creates human resource deficits, as trained health care professionals from poor countries leave for better-paying jobs in North America and Europe,<sup>18</sup> further deteriorating a country's capacity for surveillance, response, and treatment. Finally, health care systems, even in the developed world, often deliver antibiotic and antiviral medications indiscriminately, causing microbial adaptation. These practices can result in changes in the virulence of pathogens and development of resistance to frontline medications (e.g., multidrug-resistant TB, HIV, or streptococcal infections).

#### THE EPIDEMIOLOGIC TRANSITION FROM INFECTIOUS TO NONCOMMUNICABLE DISEASES: A DOUBLE BURDEN IN RESOURCE-POOR COUNTRIES

Here [in Chennai, India], juxtaposed alongside the stick-thin poverty, the malaria and the AIDS, the number of diabetics now totals around 35 million and counting. . . . The conventional way to see India is to inspect the want—the want for food, the want for money, the want for life. . . . But there is another way to see it. In a changing India, it seems to go this way: make good money and get cars, get houses, get servants, get meals out, get diabetes.

N. R. Kleinfeld (2006)

The spread of infectious diseases in a changing and interdependent world is to be expected, given increased human migration and trade. Less ob-

vious is how, and why, noncommunicable diseases (NCDs) seem to have global dimensions. Noncommunicable or chronic diseases include cardiovascular diseases, cancers, diabetes, respiratory diseases, and mental illness. Human behavior, such as high-fat/high-caloric diets, sedentary lifestyles, cigarette smoking, consumption of alcoholic beverages, and stressful lifestyles, is a primary cause of NCDs, which means that they are largely preventable.

The burden of NCDs was once felt disproportionately in highly industrialized countries. However, chronic diseases are now the major cause of death and disability worldwide and increasingly affect people from resource-poor countries.<sup>19</sup> The latest available data (from 2001) show that chronic diseases contributed to 59 percent of the 56.5 million total reported deaths in the world and 46 percent of the global burden of disease. If the trend continues, by 2020 NCDs will account for 80 percent of the global burden of disease, causing seven out of every ten deaths in developing countries.<sup>20</sup> The ability of resource-poor countries to prevent and treat NCDs is undermined by impoverished socioeconomic conditions and inadequate health systems.<sup>21</sup>

What is causing the epidemiologic transition from infectious to chronic diseases, and why have high-risk behaviors moved from richer to poorer countries? High-risk lifestyles were once thought to be associated with abundance and excessive consumption. The affluent were more likely to consume high-energy diets and work in white-collar jobs with less physical activity. Smoking cigarettes and drinking fine wine and spirits were glamorous pursuits. Cinema, television, and magazines displayed images of well-heeled men and women, with successful careers and vibrant lifestyles, smoking and drinking. The poor seemed to have a different set of problems: malnutrition rather than overeating, lives filled with hard work rather than leisure, and lives cut short from injuries and infections rather than chronic disease.

Yet, just as infectious diseases move and change, so do NCDs.<sup>22</sup> The global rise in NCDs reflects significant transformations in diet habits, physical activity levels, and tobacco use worldwide. The process of industrialization, urbanization, economic development, and increasing food market globalization has led to harmonization of behavior.<sup>23</sup> What was once culturally attractive primarily in industrialized countries has gained popularity all over the world. Visit any major city and witness the effects of a blended culture inspired by multinational corporations, media conglomerates, and the influence of tourists and immigrants as they travel

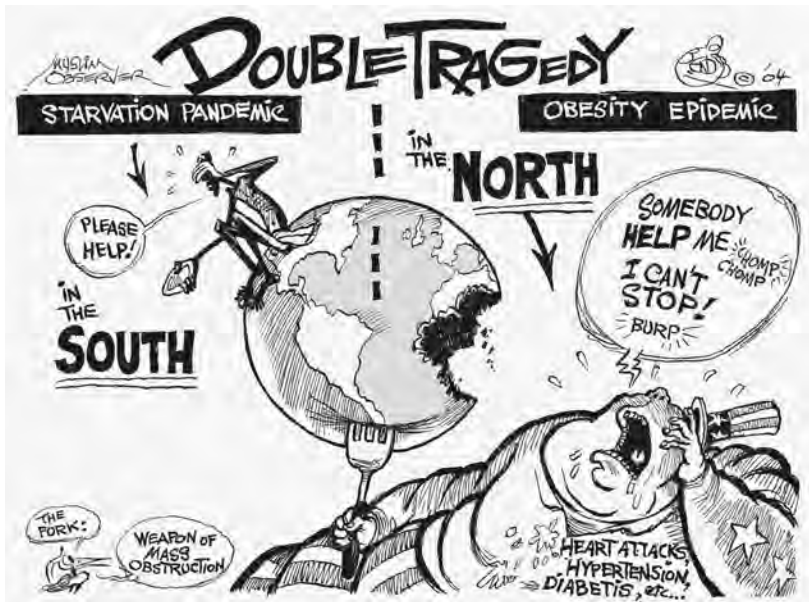


Photo 14. Chronic starvation versus epidemic obesity: Who's to blame? With the growing number of obese Americans and individuals suffering from heart attacks, hypertension, and diabetes, the U.S. government is criticized for its citizens' overconsumption and poor health. © Bendib.com. All rights reserved.

globally. The High Streets are filled with food chains such as McDonald's, Burger King, KFC, and Dunkin' Donuts; the billboards display omnipresent images of Camel cigarettes, Hershey's chocolate, Coca-Cola, and Johnnie Walker whiskey; and movies and television continue to run attractive images of alluring people smoking cigarettes and drinking alcoholic beverages. This is how risk behavior migrates from place to place and permeates all people and cultures. Perversely, as developing countries begin to grow and prosper, the emergence of behaviorally related chronic diseases stands out as a "joint totem" of success.<sup>24</sup>

"It makes little sense to expect individuals to behave differently from their peers," wrote Geoffrey Rose in 1992.<sup>25</sup> The problem is that one's peers used to be neighbors, and so behavior varied across places according to cultural norms. Today the influences on behavior are broad and diffuse. In the age of the Internet, cable television, multinational corporations, and global markets, it is rarely possible to change behavior solely

through action at a local, state, or even national level. Governments cannot meaningfully effect behavior change without global cooperation and solutions based on a shared commitment to health.<sup>26</sup> It is for this reason that public health law must transcend frontiers.

### *Global Governance for Health*

Globalization, as the previous section demonstrates, is a powerful force, propelling people, pathogens, goods, and even cultures to far-off places. Consequently, there is a demonstrable need for global cooperation and governance in world health.<sup>27</sup> The very purpose of international law is to address grave problems of transnational significance that no single country can solve on its own. International health law, however, has a number of structural weaknesses—e.g., vague standards, ineffective monitoring, weak enforcement—and a “statist” approach that insufficiently harnesses the creativity and resources of nonstate actors and civil society, including businesses, charitable foundations, and NGOs. The question of whether international law can, or should, govern the diverse entities that influence global health is a subject of intense debate in the field.<sup>28</sup> Indeed, modern cutting-edge global health governance initiatives, such as the Global Fund, Global Health Security Initiative (GHSI),<sup>29</sup> International Drug Purchase Facility (UNITAID),<sup>30</sup> and International Finance Facility for Immunization (IFFIm),<sup>31</sup> eschew formal international legal regimes.

#### INTERNATIONAL HEALTH LAW: WHO'S “THIN” RECORD OF LAWMAKING

Global health should be a major focus of international law, but that has not been the case. The WHO Constitution envisaged a normative institution that would use law, and exercise powers, to proactively promote the attainment of “the highest possible level of health.” But the agency has never met these key expectations, although it is beginning to do so.

The WHO Constitution grants the agency extensive normative powers to adopt conventions (Art. 19), promulgate regulations (Art. 21), make recommendations (Art. 23), and monitor national health legislation (Art. 63) (see figure 26).<sup>32</sup> WHO's treaty-making and regulatory powers are noteworthy. The agency can adopt binding conventions or agreements under Article 19, which, unlike normal treaties, affirmatively require states to “take action”—submitting the convention for ratification and notifying the Director-General of the action taken and state's

The World Health Organization

A specialized U.N. agency established in 1946 for the coordination of international health activities.

Mission: "Attainment of the highest possible level of health for all people."

Definition of Health: "A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."

Powers

Activities

Article 19: Adopt resolutions and agreements pertaining to health

The Framework Convention on Tobacco Control (2005) is the first convention adopted by the WHO

Article 21: Adopt regulations concerning sanitary, diagnostic, and labeling standards

International Health Regulations (adopted 1951, revised 2005)

Article 23: Disseminate recommendations, which are nonbinding but scientifically authoritative

International Code of Marketing of Breast-Milk Substitutes (1981)

Article 63: Member states must notify WHO of important health laws

Manual of the International Statistical Classification of Disease, Injuries, and Causes of Deaths (1957)

New image file to be provided? SMH/ICS

Int'l Digest of Health Legislation (1948)

Major Initiatives

Health for All emphasizes accessible and equitable primary health care as a main priority of the WHO.

The Global Outbreak Alert and Response Network is a technical collaboration for rapid identification and response to outbreaks of international importance.

Global Strategy for Diet, Physical Activity, and Health

3 by 5 was a global target to provide 3 million people worldwide living with HIV/AIDS with antiretroviral medication by 2005.

Figure 26. The World Health Organization.

reasons within eighteen months.<sup>33</sup> WHO's quasi-legislative powers under Article 21 empower the agency to adopt regulations on a broad range of health topics—e.g., international epidemics; the safety, potency, and advertising of biologicals and pharmaceuticals; and a nomenclature for diseases, causes of death, and public health practices. WHO regulations, unlike most international law, are binding on member states unless they proactively “opt out.” Once adopted by the World Health Assembly (WHA), the regulations apply to all WHO member countries, even those that voted against it, unless the government specifically notifies WHO that it rejects the regulation or accepts it with reservations.

WHO's normative powers, therefore, are extraordinary. It possesses the authority to oblige states to take health treaties seriously by submitting them to a national political process and informing the international community of the result. Its regulatory powers are even more far-reaching, as states can be bound by health regulations without the requirement to affirmatively sign and ratify. States, moreover, have ongoing duties to make annual reports to the agency on actions taken pursuant to recommendations, conventions, and regulations, as well as to provide annual reports.<sup>34</sup>

Despite WHO's impressive normative powers, modern international health law is remarkably thin—two of the three existing international health instruments predate the agency. The WHA, at its first session in 1948, adopted World Health Regulation No. 1, Nomenclature with Respect to Diseases and Causes of Death, which formalized a long-standing international process on the classification of disease.<sup>35</sup> By providing standardized nomenclature, the regulation facilitates the international comparison of morbidity and mortality data. The Nomenclature Rule was modest at its onset, but subsequently became merely advisory and is now known as the International Classification of Diseases. The Rule is, therefore, technical, rather than normative, and recommended rather than obligatory.

World Health Regulation No. 2, the International Health Regulations (IHR), discussed below, dates back to a series of European sanitary conferences held in the second half of the nineteenth century. Before the IHR were fundamentally revised in 2005, they applied to a limited number of infectious diseases.

The WHO did not create a health convention until 2003, when the WHA adopted the Framework Convention on Tobacco Control (FCTC) (see below).<sup>36</sup> Although a laudable achievement, the FCTC is almost *sui generis* because it regulates the only lawful product that is uniformly



## BOX 14

## SOURCES OF INTERNATIONAL LAW

The most authoritative statement of the sources of international law is found in Article 38 of the Statute of the International Court of Justice (ICJ),<sup>1</sup> or World Court.<sup>2</sup> Article 38 lists three primary sources: treaties, custom, and general principles. Judicial decisions and scholarly publications are secondary.<sup>3</sup>

*Treaties*<sup>4</sup> are international agreements between states and are governed by international law.<sup>5</sup> Treaties primarily govern the conduct of states and concern critical (and sometimes more mundane) national interests, such as security and commerce. However, treaties often also have a significant impact on private parties, such as corporations (e.g., trade law) and individuals (e.g., human rights). Treaties are often analogized to contracts because parties give their consent to be bound and the rules do not legally bind those who do not accept the treaty.<sup>6</sup> However, multinational treaties have important regulatory effects beyond the signatory parties.<sup>7</sup> Although treaties are far from perfect, they help bring order to relationships among IGOs, states, and citizens; provide some stability and predictability in international relations; and institutionalize norms of ethical global conduct in such vital areas as trade, human rights, health, and the environment.<sup>8</sup>

*Customary International Law (CIL)* refers to unwritten rules of international law generated by a process different from treaties.<sup>9</sup> A rule of CIL forms as a result of widespread repetition by states of similar international acts (state practice); acts taken, and not rejected, by a significant number of states; and acts that occur out of a sense

<sup>1</sup> The ICJ is the principal judicial organ of the United Nations. The court has a dual role: to settle in accordance with international law the legal disputes submitted to it by states, and to give advisory opinions on legal questions referred to it by duly authorized international bodies. UN Charter, Arts. 92-96. However, decisions of the ICJ have no binding force except between the parties to the case. Statute of the Court of the I.C.J., art. 59.

<sup>2</sup> Article 38 of the Statute of the ICJ states that in disputes submitted to it, the court shall apply: (a) international conventions establishing rules expressly recognized by contesting states; (b) international custom, as evidence of a general practice accepted as law; (c) general principles of law recognized by civilized nations; and (d) judicial decisions and the teachings of the most highly qualified publicists of the various nations, as a subsidiary means for the determination of rules of law. Article 38 does not indicate a hierarchy, but for most purposes the ICJ gives precedence to sources in the order in which they appear: treaties, customs, and general principles.

<sup>3</sup> Ian Brownlie, *Principles of Public International Law*, 6th ed. (Oxford: Oxford University Press, 2003): 5.

<sup>4</sup> Multinational treaties, the primary expression of international law, are given many names: treaties, pacts, international agreements, covenants, conventions, etc.; the same rules apply regardless of what the treaty is called. (In the United States, the term *treaty*, as contrasted with an "international executive agreement," has a particular constitutional significance.)

<sup>5</sup> The international rules governing adoption, interpretation, and validity of treaties are codified in the 1969 Vienna Convention on the Law of Treaties (VCLT).

<sup>6</sup> Treaties may also explicitly permit states to make "reservations" (qualifications, conditions, or exceptions) to provisions with which they disagree, thus sacrificing uniformity of obligation for more widespread adherence. Henry J. Steiner and Phillip Alston, *International Human Rights in Context* (Oxford: Oxford University Press, 2000). The IHR, for example, permit reservations whereas the FCTC unusually does not.

<sup>7</sup> John H. Jackson, *The World Trading System: Law and Policy of International Economic Relations*, 2d ed. (Cambridge, MA: MIT Press, 1997): 24-34 ("Notions of reciprocity and a desire to depend on other nations' observance of rules lead many nations to observe rules even when they do not want to").

<sup>8</sup> Steiner and Alston, *International Human Rights*.

<sup>9</sup> *Restatement (Third) of Foreign Relations Law of the United States* § 102 (1987) ("Customary international law results from a general and consistent practice of states followed by them from a sense of legal obligation").<sup>10</sup> A rule of CIL therefore requires a showing that it has been followed as "gen-

of legal obligation.<sup>10</sup> A rule of CIL is binding on all states, except those that persistently object. Customary rules can be fundamental but also controversial. They are fundamental because of their universal character, sometimes rising to a level of compelling international law (*jus cogens*). *Jus cogens* is a peremptory norm of international law such as the prohibition of genocide or the slave trade.<sup>11</sup> CIL can be controversial because scholars cannot easily determine when conduct attains customary status. What exactly is “consistent,” a “practice,” or a sense of “legal obligation”? Despite the conceptual and pragmatic difficulties, CIL is an essential aspect of international law, because it represents the norms of communities and nations.

*General Principles of Law* are rules of domestic law recognized widely by different national legal systems, which prove useful in international relations in the absence of treaty law or CIL. To become a general principle, a rule must be recognized in most of the world’s legal systems—i.e., common law, civil law, and significant religious law (e.g., Sharia, or Islamic law)<sup>12</sup> and ideological (e.g., socialist law) legal cultures. The most frequent use of this source of international law occurs when international tribunals apply general principles of domestic law to resolve legal questions not answered by applicable treaty law or CIL. States and international tribunals are reluctant to apply general principles of law because most of these principles were not generated to apply directly to international relations.<sup>13</sup>

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eral practice” and has been “accepted as law.” The “general practice” element is an objective inquiry: Have international actors followed the rule, and has compliance been consistent and for a sufficient period of time? The “accepted as law” element is more subjective: Have international actors observed the practice out of a sense of legal obligation or merely out of courtesy or expediency? David J. Bederman, *International Law Frameworks* (New York: Foundation Press, 2001).

<sup>11</sup> *Jus cogens* is a peremptory norm of general international law accepted and recognized by the international community as a “norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.” Vienna Convention on the Law of Treaties, art. 53, May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679.

<sup>12</sup> Sharia (also Shari’ah, Shari’a, Shariah, or Syariah) is traditional Islamic law, also known as Allah’s Law. Islam classically draws no distinction between religious and secular life. Hence, Sharia covers not only religious rituals, but many aspects of day-to-day life. “Shari’ah,” *Encyclopedia Britannica* (2005), <http://search.eb.com/eb/article-9105857>.

<sup>13</sup> *Restatement (Third) of Foreign Relations Law of the United States* § 102, comment 1 (1987).

harmful. The FCTC was politically feasible because the industry was vilified for denying scientific realities, engineering tobacco to create dependence, engaging in deceptive advertising, and targeting youth, women, and minorities.<sup>37</sup>

Prominent scholars have chastened WHO for its reluctance to create binding norms, despite the bold mission and sweeping powers granted in its constitution.<sup>38</sup> At the turn of the twenty-first century, more than fifty years after its founding, the agency had failed to adopt a single treaty. And its two regulations—on disease classification and epidemic control—were largely historical, limited in scope, and lacking in real-world impact. Since that time, WHO has been far more proactive, suggesting that it may be prepared to exercise political power when necessary to avert global health crises. The evolution in thinking can be traced to the SARS

outbreaks when WHO issued politically controversial travel advisories with severe economic impacts. In the FCTC, the agency demonstrated a willingness to take on a powerful industry. And the revised IHR were, in many respects, the high-water mark for the exercise of normative power, as the agency exerted its influence on matters ranging from capacity building and global surveillance to trade and human rights. The critical question, however, is whether the WHO can build on these recent achievements to deal with the most important, and intractable, health problems in the poorest regions of the world.

There are a number of important areas of international law that influence global health, even if they do not achieve fully effective global health governance. The remainder of this chapter explores major advances in the fields of infectious disease control, tobacco, trade, and human rights. To better understand these global initiatives, it will be helpful to review the principal sources of international law in box 14.

#### INTERNATIONAL HEALTH REGULATIONS: A HISTORIC DEVELOPMENT IN GLOBAL GOVERNANCE

The origins of the International Health Regulations (IHR)—the only global rules governing the international spread of infectious disease—date back to the first International Sanitary Conference, held in Paris in 1851 to address the European cholera epidemics.<sup>39</sup> During the latter half of the nineteenth century, ten sanitary conferences were held and eight conventions negotiated (though most did not come into force) to address the transboundary effects of infectious diseases.<sup>40</sup> The International Sanitary Convention dealing with cholera, plague, and yellow fever was adopted in Venice in 1892, followed by a convention dealing with plague in 1897.<sup>41</sup> In 1903, a new International Sanitary Convention replaced the conventions of 1892 and 1897.<sup>42</sup>

At the turn of the twentieth century, the international community established regional and international institutions to enforce these conventions. American states set up the International Sanitary Bureau (ISB) in 1902, which became the Pan American Sanitary Bureau (PASB), a precursor to the Pan American Health Organization (PAHO).<sup>43</sup> In 1907 European nations developed their own multilateral institution, the Office International d'Hygiène Publique (OIHP).<sup>44</sup> The Health Organization of the League of Nations (HOLN) was formed in 1923, between the two world wars. Article 23 of the League of Nations Covenant meekly stated

that members would “endeavor to take steps in matters of international concern for the prevention and control of disease.”<sup>45</sup> The ISB, OIHP, and HOLN were separate institutions, without harmonization in goals or practices.

The United Nations was established after the horrors of World War II, and one of its primary functions was the protection of global health.<sup>46</sup> The World Health Organization (WHO) was the first international agency established by the United Nations.<sup>47</sup> Its preamble expresses universal aspirations,<sup>48</sup> stating that its “principles are basic to the happiness, harmonious relations and security of all peoples.”<sup>49</sup>

Pursuant to the agency’s Article 21 power, WHO member states adopted the International Sanitary Regulations (ISR) on July 25, 1951. The ISR were renamed the International Health Regulations (IHR) in 1969. The IHR initially applied to six diseases—cholera, plague, relapsing fever, smallpox, typhus, and yellow fever—but were slightly modified in 1969<sup>50</sup> (to exclude louseborne typhus and relapsing fever) and again in 1981<sup>51</sup> (to exclude smallpox, in view of its global eradication). By the early 1980s the IHR applied only to cholera, plague, and yellow fever—the same diseases originally discussed at the first International Sanitary Conference in 1851. Thus, before the IHR were fundamentally revised in 2005,<sup>52</sup> their scope and approach were similar to that of the ISR in the mid-twentieth century.

The fundamental reform of the IHR that took place in 2005 would not have been possible were it not for a confluence of events that raised infectious diseases to the realm of “high politics.”<sup>53</sup> The WHA resolved in 1995 to revise the IHR in response to frightening outbreaks of cholera in Peru, the plague in India, and Ebola hemorrhagic fever in Zaire.<sup>54</sup> During this time, the world was also facing one of the greatest pandemics in global history, HIV/AIDS,<sup>55</sup> as well as the looming threats of SARS,<sup>56</sup> avian influenza,<sup>57</sup> Marburg,<sup>58</sup> and bioterrorism.<sup>59</sup> The potentially drastic economic and security consequences of these health threats made it politically difficult to oppose an ambitious reform of international infectious disease law.

The IHR (2005) contain sixty-six articles organized into ten parts, with nine annexes. The rules expand WHO jurisdiction beyond a narrow band of infectious diseases to the entire spectrum of public health risks of international importance. The IHR focus on key aspects of global preparedness, ranging from surveillance and capacity building to public health response and border control. The cumulative effect of reforms could transform WHO’s role and stature in international law and es-

establish a coherent structure for systematic detection and intervention in the face of global health threats.<sup>60</sup>

*Purpose, Scope, and Principles: Health, Trade, and Human Rights*

The IHR are expansive in scope, covering “public health risks”<sup>61</sup> and “public health emergencies of international concern.”<sup>62</sup> Consequently, WHO has authority to act in most contexts where an event has health-related transnational dimensions, which include biological, chemical, and radio-nuclear health risks. Since the source of the hazard is immaterial, WHO possesses jurisdiction for events that are naturally occurring, accidental, and intentional.<sup>63</sup>

The purpose of the IHR is “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade” (Art. 2). The IHR therefore balance the need for health regulation with trade interests. Health measures cannot be more stringent than what is needed to avert or ameliorate the public health risk; state action must be rooted in scientific evidence.<sup>64</sup> The IHR interact with international trade law in interesting, important ways, with both areas of law focusing on the legitimacy of state health measures that adversely affect international commerce.

The IHR balance not only health with trade, but also health with human rights.<sup>65</sup> The IHR have “universal application for the protection of all people of the world,” and States Parties must have “full respect for the dignity, human rights and fundamental freedoms of persons” (Art. 3). Health measures taken must be applied in a transparent and nondiscriminatory manner (Art. 42). States Parties must, in particular, treat international travelers with “respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress”; respectful treatment requires consideration of travelers’ gender, culture, ethnicity, and religion (Art. 32).

The balancing dynamic in the IHR, then, includes adherence to scientific methodologies, the flow of trade and travel, and respect for human rights (see figure 27). In each of these realms, there are difficult trade-offs:

- When can countries act in the face of scientific uncertainty?
- How much interference with economic freedom can be tolerated

Trade and Travel	Scientific Methodologies	Human Rights
<ul style="list-style-type: none"><li>• Consider risk of interfering with international traffic when determining if an event is a public health emergency (Art. 12)</li><li>• No ship or aircraft shall be prevented from calling at a port of entry for public health reasons unless the point of entry is unable to apply health measures (Art. 28)</li><li>• Unless otherwise authorized, goods in transit without transshipment that are not live animals will not be subject to IHR health measures or detained for public health purposes (Art. 33)</li><li>• Health measures shall not be more restrictive to international traffic than reasonably available alternatives that would achieve the appropriate level of health protection (Art. 43)</li><li>• States implementing additional health measures that significantly interfere with international traffic shall provide WHO with rationale and relevant scientific information (Art. 43)</li></ul>	<ul style="list-style-type: none"><li>• Determination of a public health emergency of international concern based on scientific principles, available scientific evidence and other relevant information (Art. 12)</li><li>• Determination of whether to implement health measures based on scientific principles and available scientific evidence of risk to health (Art. 43)</li><li>• Consultation between states impacted by an emergency and states implementing health measures to clarify scientific information and public health rationale underlying implemented health measures (Art. 43)</li></ul>	<ul style="list-style-type: none"><li>• IHR implementation shall be with full respect for the dignity, human rights and fundamental freedoms of persons (Art. 3)</li><li>• No IHR medical examination, vaccination, prophylaxis or health measure will be performed on travelers without prior informed consent, except as otherwise noted (Art. 23)</li><li>• States shall minimize discomfort or distress from IHR measures by treating all travelers with courtesy and respect and taking into consideration gender, sociocultural, ethnic or religious concerns of travelers (Art. 32)</li><li>• Health measures pursuant to the IHR shall be applied in a transparent and non-discriminatory manner (Art. 42)</li><li>• Health information collected or received under the IHR referring to an identifiable person shall be kept confidential and processed anonymously, unless otherwise mentioned (Art. 45)</li></ul>

Figure 2.7. The International Health Regulations’ (IHR) balancing dynamic.

in the name of health? And who should bear the financial cost of health regulation?

- When should personal autonomy, privacy, and liberty yield for the sake of the public's health and safety?

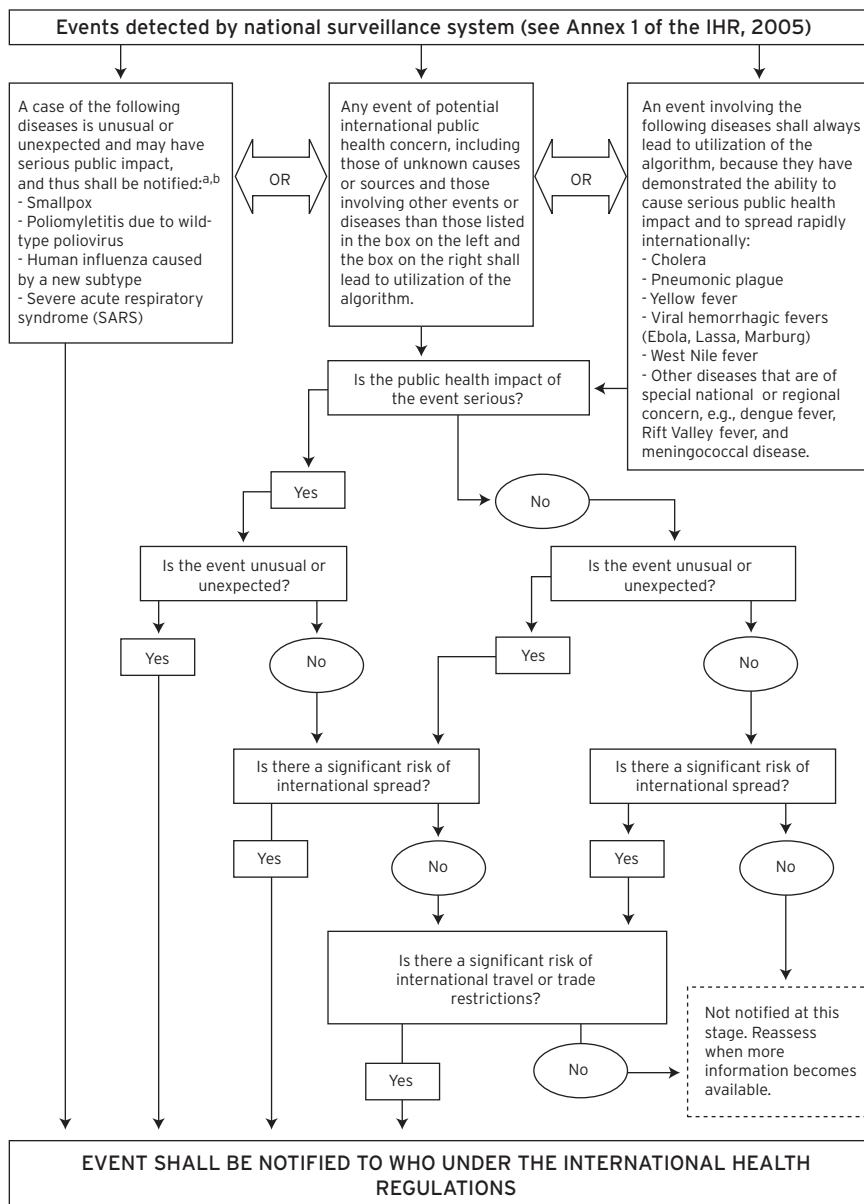
### *Core National Capacities for Public Health Preparedness*

States Parties have the duty to develop, strengthen, and maintain core public health capacities to detect, assess, notify, and report events; and to respond promptly and effectively to public health risks and emergencies of international concern (Arts. 5[1], 13(1), and Annex 1). Global health protection relies on the ability of national and subnational governments to engage in speedy and accurate surveillance and response to health threats.

The mandate to build public health infrastructures is powerless, however, without adequate resources for poor countries, where in some cases the per capita annual spending on health is unconscionably low. The least developed countries spend between \$1 and \$25 per capita per year on health care; in contrast, developed nations spend between \$1,500 and \$4,500.<sup>66</sup> The World Health Assembly urged member states to “mobilize the resources necessary” and to provide support upon request “in the building, strengthening and maintenance of public health capacities.”<sup>67</sup> Although the IHR ask States Parties to provide financial and technical resources, these provisions are either nonbinding<sup>68</sup> or weak;<sup>69</sup> they require states to comply only “to the extent possible.” Similarly, WHO duties to provide surveillance and response assistance<sup>70</sup> do not address WHO's own shortage of funds and personnel. Given the financial demands created by other global health problems, such as the need to increase access to HIV/AIDS treatment<sup>71</sup> and meet the health-related Millennium Development Goals,<sup>72</sup> the IHR's silence on how the economic demands of the core-capacity objectives will be met is a serious problem for which the IHR provide no apparent answers or strategies.

### *Surveillance*

The IHR, cognizant of past recalcitrance of member states to communicate promptly and fully events that pose health risks, provide detailed requirements for data dissemination. The new approach is radical because it does not limit surveillance and reporting requirements to a narrow list



<sup>a</sup> As per WHO case definitions.

<sup>b</sup> The disease list shall be used only for purposes of these Regulations.

Figure 28. Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern.

Source: World Health Organization, "Decision Instrument for the Assessment and Notification of Events That May Constitute a Public Health Emergency of International Concern," February 22, 2005, [www.who.int/gb/ghs/pdf/IHR\\_IGWG2\\_ID4-en.pdf](http://www.who.int/gb/ghs/pdf/IHR_IGWG2_ID4-en.pdf).



of diseases, but instead requires States Parties to *notify* WHO within twenty-four hours of all events in their territory<sup>73</sup> that may constitute a “public health emergency of international concern” (Art. 6) (see figure 28).<sup>74</sup> States Parties must *share all relevant public health information* during an unexpected or unusual public health event, irrespective of origin or source, that may constitute a public health emergency of international concern (Art. 7). This power implies a state obligation to share data about accidental or intentional health hazards,<sup>75</sup> an obligation that became highly politicized in intergovernmental negotiations.<sup>76</sup> States Parties must also *consult and keep WHO apprised* of events that may not be notifiable due to incomplete scientific information (Art. 8).

The IHR authorize WHO to take into account unofficial sources of information (e.g., NGOs and independent scientists), which must be assessed according to established epidemiological principles (Arts. 9, 10). This power enables WHO to utilize the broad network of potentially important surveillance data available in the age of the Internet and other electronic information systems. The Global Outbreak Alert and Response Network (GOARN), based on this concept, is a collaboration of institutions and networks that pool human and technical resources for the rapid identification, confirmation, and response to outbreaks of international importance. This network is central to the functioning of the IHR.<sup>77</sup>

The regulations require WHO to share nongovernmental information with States Parties, “and only where it is duly justified may WHO maintain the confidentiality of the source” (Art. 9[1]). This requirement to disclose the source of nongovernmental information might deter nonstate actors from supplying the WHO with information, particularly in authoritarian regimes. The IHR provide no express guidance for determining under what circumstances WHO would be justified in maintaining the confidentiality of nonstate sources.

### *Dissemination of Health Information: Privacy*

States Parties must keep personally identified or identifiable information “confidential and processed anonymously as required by national law” (Art. 45[1]). Some states and regional alliances, including the United States<sup>78</sup> and the European Union,<sup>79</sup> have data protection laws, but many others do not, which could considerably weaken the IHR’s privacy mandate. States may disclose and process personal data where “essential for the purposes of assessing and managing a public health risk,” but must

follow fair information practices. These practices require that personal data be relevant and not excessive; be accurate and current; be processed fairly and lawfully; and not be kept longer than necessary. WHO must also, as far as practicable, provide individuals with their personal data in an intelligible form and allow for correction of inaccuracies (Art. 45).

### *WHO Recommendations*

WHO has the power to issue temporary and standing recommendations. The Director-General must issue temporary recommendations upon determining that a public health emergency of international concern is occurring (Art. 15). WHO may also make standing recommendations on the appropriate health measures to be applied routinely or periodically in relation to specific ongoing public health risks (Art. 16). Article 18 contains applicable health measures for persons (e.g., medical examinations, vaccination, contact tracing, isolation, and exit screening), as well as for baggage, cargo, containers, conveyances, and goods (e.g., review of the manifest and routing documents, inspections, safe handling, seizure and destruction, and refusal of departure or entry).<sup>80</sup>

### *International Travelers*

International travel is one of the primary means by which pathogens spread across frontiers. A health measure directed at travelers can be an effective means of containing an outbreak or it can overreach, causing adverse effects on trade, tourism, and human rights (Arts. 23, 30–32, 43). A “suspect” traveler, who may have been exposed to infection<sup>81</sup> and is placed under “public health observation,” can continue an international voyage only if he or she does not present an imminent public health risk. Despite the duty to be respectful to travelers and allow their passage (Art. 30), States Parties may require, for public health purposes, information about the traveler’s destination and itinerary, and a *noninvasive* medical examination that is the least intrusive necessary to achieve the public health objective (Art. 23). Upon evidence of a public health risk, States Parties may conduct the least intrusive and invasive medical examination or other health measure necessary to achieve the objective of preventing the international spread of disease. Travelers, or their parents or guardians, must be informed of any health risk associated with vaccination or other prophylaxis, and physicians must be educated about this requirement. Similarly, medical examinations and procedures

must conform to established national or international safety standards (see further, chapter 11).

### *A New Paradigm for Global Health Governance*

The IHR offer an opportunity to improve global health governance, overcoming the problems of sovereignty and entrenched power. An innovative governance paradigm, based on the new IHR, would include:

*The salience of health over trade.* WHO should dedicate itself to the protection and promotion of global health, respecting travel and trade wherever possible. That is the vision of the WHO Constitution, which does not mention the protection of commerce.

*Wide jurisdiction.* The expansive scope of the new IHR is preferable because it is flexible, prospective, and covers all hazards (radiological, chemical, and biological), whether naturally occurring, accidental, or intentional.

*Comprehensive data collection.* The WHO could dramatically improve global surveillance by establishing standards for uniform data sets, core informational requirements, and timely monitoring and reporting; creating “small-world networks” consisting of scientists, health professionals, and NGOs to broaden the sources of health information; and using modern technology (e.g., electronic health records and the Internet) to gather and analyze surveillance data.<sup>82</sup>

*National public health preparedness.* To improve national competencies, WHO should set minimum standards for laboratories, data systems, and response capabilities. The international community should substantially increase technical and financial assistance for health system improvement in developing countries. Not only will this kind of commitment allow progressive development of higher health standards in resource-poor countries, but it is also in the interests of the industrialized world.

*Human rights safeguards.* The new IHR go a long way to respecting human rights but leave out important safeguards. The WHO could demonstrate even greater respect for human rights by applying the internationally accepted norms contained in the Siracusa Principles (discussed below), which require health measures to be necessary, proportionate, and fair.<sup>83</sup> Health

measures should be based on the rule of law and provide due process for persons whose liberty is placed in jeopardy.

*Sound public health governance.* WHO member states have not always followed basic principles of good public health governance, such as openness, nondiscrimination, and compliance with scientific methods. The WHO should set an example by establishing its policies and recommendations in an open manner, basing them on scientific evidence, and exercising power equitably. The agency gains credibility by its adherence to science, the truthfulness of its disclosures, and its fair dealings with all countries, rich and poor alike.

*The future of global health governance.* The new IHR will not assure capable leadership and sound governance by the WHO. Yet the revision offers an opportunity for a renewed commitment by the international community to a shared vision of global health. The revision gives the WHO a clear mission, significantly enhanced jurisdiction, and formal power to set standards and make recommendations. By assenting to a far-reaching revision of the IHR, member states are ceding some control over global health threats and have taken a vital step toward better protection against the biological, chemical, and radiological hazards posed in the modern age.

#### FRAMEWORK CONVENTION ON TOBACCO CONTROL: GLOBAL STRATEGIES TO REDUCE SMOKING

The WHO has turned to international law solutions in the area of chronic disease as well as infectious disease. Particularly remarkable is the adoption of the Framework Convention on Tobacco Control (FCTC).<sup>84</sup> The FCTC, the first treaty negotiated under WHO auspices, was a decade in the making.<sup>85</sup> The convention was initiated in 1995<sup>86</sup> and adopted by the World Health Assembly in 2003,<sup>87</sup> and it entered into force on February 27, 2005.<sup>88</sup>

The FCTC arose in response to the human, social, and economic costs of the tobacco pandemic. More than 1.25 billion smokers inhabit the earth today, representing approximately one-third of the adult population.<sup>89</sup> Cigarette smoking is a leading cause of preventable death and disability worldwide, killing around 4.9 million people each year; smoking is projected to kill about 10 million people annually by 2020,

with two-thirds in developing countries.<sup>90</sup> Once confined largely to industrialized nations, the burden of disease and death is rapidly shifting to low- and middle-income countries, as a result of rising incomes, trade liberalization, the emancipation of women, and global marketing and communications.<sup>91</sup> Compounding the immense death toll are the economic implications of cigarette and passive smoking. In the United States, the social cost of smoking (i.e., costs shared by the public) is an average of \$106,000 for every woman and \$220,000 for every man who smokes; this price includes the cost of health care related to second-hand smoking, and increased Medicare, Medicaid, and Social Security payments.<sup>92</sup>

The FCTC's global strategy was also thought necessary to counteract an economically and politically powerful multinational industry.<sup>93</sup> The tobacco industry for decades denied the reality of addiction, disease, and death; engineered the product to create and maintain dependence; engaged in deceptive advertising; targeted youth, women, and minorities; and aggressively blocked national legislation.<sup>94</sup> Consider Philip Morris's opposition to tobacco regulation in the Czech Republic, arguing that smoking had saved the government \$147 million due to smokers' early deaths.<sup>95</sup> The company itself later conceded that the report exhibited "terrible judgment [and] disregard of basic human values."<sup>96</sup> Undeterred, the industry has aggressively pursued new markets in Latin America, Eastern Europe, Africa, and newly industrializing economies in Asia such as China, India, Indonesia, and Thailand.<sup>97</sup>

### *Objectives, Principles, and Legal Force*

The FCTC's declared objective is to protect present and future generations from "the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke (Art. 3)." It aims to keep citizens informed of the health hazards and to facilitate political commitment, international cooperation, and financial assistance (Art. 4). It mandates that States Parties develop and implement comprehensive multisectoral national tobacco control strategies (Art. 5).

Although it requires national tobacco control strategies, the FCTC rarely contains specific standards that countries must meet. Framework conventions typically establish broadly stated goals and avoid the more onerous commitments normally embodied in a conventional treaty. This has the distinct advantage of helping to build a global consensus on a

politically charged public health issue. However, the framework convention approach is vulnerable to the critique that it uses “hortatory rather than legal statements, soft rather than hard law, and denies [the FCTC] of any self-executing requirements.”<sup>98</sup> The FCTC expresses non-obligatory legal language throughout: “recognize,” “consider,” “guidelines,” “endeavor to,” and “without prejudice to the sovereign right of the Parties.” Consequently, signing the treaty can be seen as relatively cost-free because states become bound by more rigorous commitments only if they consent subsequently to negotiated protocols.<sup>99</sup> It is perhaps because the rules established were so elastic that President George W. Bush signed the FCTC. Even so, the United States has not ratified the treaty.<sup>100</sup>

Despite its deficits in standard setting, implementation, and monitoring, the FCTC establishes a blueprint for comprehensive tobacco control activities that nations can emulate. The FCTC adopts several strategies: demand reduction, supply reduction, and tort litigation.

#### *Reduction of Demand for Tobacco*

Articles 6–14 of the FCTC establish core demand-reduction strategies, including price and tax measures, as well as nonprice measures. Tax and price policies are designed to reduce demand for cigarettes. Data show that taxation and high prices reduce smoking, particularly among consumers without significant disposable income, such as children and adolescents.<sup>101</sup> States Parties are required to report cigarette tax rates and tobacco consumption trends (Arts. 6, 21). Countries are also urged to restrict or prohibit duty-free tobacco sales to prevent importation and smuggling (Art. 6(3)). Nonprice measures include protection from exposure to tobacco smoke (e.g., workplaces, indoor public places, and public transport); regulation of the contents of tobacco products; and disclosure requirements for manufacturers (Arts. 6–10). These measures are designed to inform consumers about the risks and reduce exposure to environmental tobacco smoke.

The FCTC regulates the packaging, labeling, advertising, and promotion of tobacco products (Arts. 11–13). Packaging and labeling regulation is designed to deter false, misleading, or deceptive messages that create an erroneous impression (e.g., “low tar,” “light,” “ultra light,” or “mild”). The treaty obliges States Parties to adopt and implement large, clear, visible, legible, and rotating health warnings and messages on to-

bacco products, occupying at least 30 percent of the principal display areas. (See, e.g., the graphic images on cigarette packets in Australia.)

Tobacco products are advertised and promoted through sports events, music festivals, films, and fashion—in fact, anywhere the tobacco industry can target potential new smokers. Cigarettes are often associated with ideas and images that convey adventure, glamour, and vitality. Tobacco advertisements frequently target minorities, women, and young people. Recognizing the pervasive effects of marketing, the FCTC calls for a comprehensive ban on tobacco advertising, promotion, and sponsorship. In deference to politically powerful countries, however, the FCTC states that such regulation should be in accordance with the country's constitutional principles (Art. 13). The U.S. Supreme Court, for example, has strongly defended commercial speech (see chapter 9), and to a lesser extent, one can see similar constitutional arguments in Canada<sup>102</sup> and Europe.<sup>103</sup>

### *Reduction of Supply of Tobacco*

Articles 15–17 of the FCTC establish core supply-reduction strategies, including measures to control illicit trade and sales to minors, as well as to create economically viable alternatives to tobacco production. The illicit trade in cigarettes—smuggling, unlawful manufacturing, and counterfeiting—is found throughout the world. The illicit trade makes international brands more affordable and enables smugglers to evade health regulations. Measures in the FCTC include marking unit packets with the product's origin and, for domestic sales, a statement that they can be sold only in that country. Countries are required to monitor and collect data on cross-border trade and enact penalties for unlawful purchase, sale, and transport (Art. 15).

Tobacco use among young people is pervasive. Most tobacco use starts during childhood and adolescence, and statistics indicate an upward trend in tobacco initiation and use among young persons.<sup>104</sup> Tobacco is available to children in many countries, even countries with legal prohibitions. Young people's access to tobacco is a serious problem due to the addictive and psychosocial effects of smoking.<sup>105</sup> Recognizing these adverse effects, the FCTC requires States Parties to prohibit sales to minors and ensure effective implementation. The treaty, for example, calls for prominent signs at the point of sale, bans on sweets and toys in the form of cigarettes, and inaccessibility of vending machines to young people (Art. 16).

The FCTC requires States Parties to promote economically viable alternatives for tobacco workers, growers, and sellers (Art. 17). The purpose is to create economic incentives for the workforce to discontinue tobacco production in favor of more socially beneficial activities.

### *Civil and Criminal Liability*

Tobacco litigation strategies in the United States were influential in the negotiations on the FCTC. Although not entirely successful, litigation changed the social and political culture of tobacco and had a deterrent effect on the most egregious industry practices.<sup>106</sup> Most regions of the world are not as litigious as the United States. Still, Article 19 asks States Parties to consider criminal and civil liability for the tobacco industry. Because the industry is so powerful and skilled at defending against liability, the FCTC promotes international cooperation such as information exchange and legal assistance. More generally, the FCTC contains provisions encouraging reporting, scientific and technical cooperation, and communication of information (Arts. 20–22).

### *The FCTC's Future Effectiveness*

The future effectiveness of the FCTC is difficult to predict. Certainly, the treaty was a momentous achievement in global health governance. It forged a global consensus to combat a devastating health hazard—a rare event in international relations. Even without enforceable norms, the FCTC sets out a comprehensive program for smoking prevention and cessation.<sup>107</sup>

At the time of its adoption, the rate of smoking in the industrialized world was already abating—the result of a decades-long campaign of legislation, litigation, and health education. The same dynamic could occur in low- and middle-income countries as they follow the FCTC's core strategies. To achieve this global public good for health will require considerable political will and economic resources from the international community.

## WORLD TRADE AND WORLD HEALTH

Too much of this century was marked by force and coercion. Our dream must be a world managed by persuasion, the rule of law, the settlement of differences



peacefully within the law and cooperation. It's a good thing that all our living standards are now based on the ability of our neighbours to purchase our products. That's where the WTO can do splendid work and advance the progress of the human species.

Mike Moore, speech to the  
Transatlantic Business Dialogue, Oct. 29, 1999

What is called "globalization" is a specific form of international integration, designed and instituted for particular purposes. There are many possible alternatives. This particular form happens to be geared to the interests of private power, manufacturing corporations and financial institutions, closely linked to powerful states. Effects on others are incidental. Sometimes they happen to be beneficial, often not.

Noam Chomsky, interview with *Washington Post*  
readers: "Globalization and Its Discontents with  
Noam Chomsky," May 16, 2000

The trading of goods and services from one area to another, across political and geographic boundaries, is pervasive.<sup>108</sup> The movement of products and knowledge along routes of trade is the engine that drives economies, but it is also the means by which disease is spread and cultures are homogenized. Trade can provide nations with resources or technological advances to which they would not otherwise have access. It opens markets to life-saving products such as medicines or medical equipment, and to life-threatening products such as tobacco or asbestos. It also can make essential medicines, such as antiretroviral medication for HIV/AIDS, so expensive that they are out of reach for the poor. Trade in services can reallocate expertise where it is needed or drain an area of its human capital. International trading systems can (for better or worse) change the way nations regulate their products. Trade may also provide an avenue for the exchange of ideas, information, and culture.<sup>109</sup>

In short, the effects of trade on prosperity and health are deeply complex.<sup>110</sup> To those who embrace capitalism and competitive markets, trade is the answer to many socioeconomic problems. To those who prefer equity and social distribution, trade liberalization places the interests of rich countries and multinational corporations ahead of the health and lives of the world's poor.

Like it or not, trade is a social, political, and economic reality. In the

late twentieth century, countries joined together to form the World Trade Organization (WTO), setting trade into a global system of governance. The current trade system has as its goals providing predictability and stability and reducing barriers to trade so as to increase the standard of living for all.<sup>111</sup> The WTO's principal mission is the reduction of trade barriers, but it cannot escape the inexorable links between commerce and health. The goal of a rational trade system should be to find a balance between economic prosperity and health protection.

### *The World Trade System: Origins and Objectives*

The framework for the modern world trade system originated after World War II with the Bretton Woods Accord, which led to the creation of the International Monetary Fund (IMF), the World Bank, and the General Agreement on Tariffs and Trade (the GATT). The GATT, developed in 1947 and superseded by GATT 1994, was designed to liberalize trade by reducing tariff (e.g., import and export duties) and nontariff (e.g., import quotas, licensing, and health and safety standards) trade barriers.

Under the auspices of the GATT, the contracting parties agreed to hold periodic multinational negotiations ("Rounds"). The Uruguay Round, in 1986–94, culminated in the establishment of the WTO on January 1, 1995.<sup>112</sup> The WTO Agreement sets forth its objectives:

Raising standards of living, ensuring full employment, . . . and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources [for] sustainable development . . . [and ensuring] that developing countries . . . secure a share in the growth in international trade.<sup>113</sup>

The WTO founders, therefore, intended trade expansion to be environmentally sound, and aspired not to leave the least developed countries behind. Yet, more than a decade later, there still exists bitter controversy over the effects of trade on health, the environment, and economic development for the poor.

The WTO includes a package of agreements, notably GATT 1994<sup>114</sup> and the General Agreement on Trade in Services (GATS).<sup>115</sup> The WTO agreements most relevant to health include:<sup>116</sup> the GATT 1994; Sanitary and Phytosanitary Measures (SPS); and Trade-Related Aspects of Intellectual Property Rights (TRIPS) (see table 9).<sup>117</sup> Regional trade pacts such as the North American (NAFTA) and Central American (CAFTA) Free Trade Agreements also affect commerce and health.<sup>118</sup>

TABLE 9. WTO agreements relevant to health

WTO Agreement	Mission	Health Area	Enforcement
1994 General Agreement on Tariffs and Trade (GATT 1994)	Liberalize trade and increase market access by decreasing tariffs and other trade barriers	Article 20(b): exception allowing imposition of trade restrictions to protect the health of humans, animals, and plants, e.g., cigarettes, air pollution, asbestos	“The provisions of this Agreement shall apply to the metropolitan customs territories of the contracting parties” (Art. 24) Contracting parties “may authorize a contracting party or parties to suspend the application to any other contracting party or parties of such concessions or other obligations under this Agreement as they determine to be appropriate in the circumstances” (Art. 23)
Sanitary and Phytosanitary Measures (SPS)	Harmonize sanitary and phytosanitary measures internationally to protect human, animal, and plant health	Regulation of goods that may carry disease or disease-causing organisms and consumables that contain contaminant additives, contaminants, or to xins creating a risk to health, e.g., beef hormones, genetically modified foods	“Members are fully responsible under this Agreement for the observance of all obligations set forth herein” (Art. 13) Articles 22 and 23 of GATT 1994 govern dispute settlements and consultations (Art. 11)
Trade-Related Aspects of Intellectual Property Rights (TRIPS)	Promote effective intellectual property rights protection, especially patenting and licensing	Article 31: compulsory licensing in national emergencies, e.g., HIV/AIDS anti-retrovirals	“Members shall give effect to the provisions of this Agreement” (Art. 1). Articles 22 and 23 of GATT 1994 govern dispute settlements and consultations (Art. 64) “Members shall ensure that enforcement procedures . . . are available under their law so as to permit effective action against . . . infringement of intellectual property rights” (Art. 41)

## BOX 15

### WTO STRUCTURE

#### Membership

WTO membership is not automatic. Countries must negotiate their entry into the WTO system with existing members. Currently, there are 148 member states, accounting for more than 90 percent of world trade.<sup>1</sup>

#### Decision Making

WTO decisions are made by various bodies.<sup>2</sup> The Ministerial Conference, which meets at least biennially and comprises all WTO members, is the highest decision-making body. The General Council has executive authority over day-to-day operations of the WTO. Its members also meet as the Dispute Settlement Body.

#### Dispute Settlement

Member states that believe they have been injured by other members' violation of WTO obligations can seek redress before the Dispute Settlement Body. The Dispute Settlement Body then convenes a panel to hear and decide the case. Panel decisions can be appealed to the Appellate Body (AB), a standing body of seven members with expertise in law and international trade.<sup>3</sup> Decisions of the AB become final and binding, unless the Dispute Settlement Body unanimously decides otherwise.

<sup>1</sup> WHO Secretariat and WTO Secretariat, *WTO Agreements and Public Health* (Geneva: World Trade Organization, 2002): 28.

<sup>2</sup> Marrakesh Agreement, Art. 9. Decision-making bodies are technically comprised of representatives from all member states, who can be government officials or representatives of observer organizations.

<sup>3</sup> AB members are elected by the Dispute Settlement Body for terms of four years. Usually, three members of the AB hear a controversy.

### *Basic Principles of International Trade: Nondiscrimination*

The general principles of “most favored nation” (MFN) and “national treatment” guide the substance of WTO agreements. These principles are designed to prevent discrimination between trading partners and avert protectionist trade measures. Under the MFN principle, a benefit granted to one country in regard to a product must be granted to all WTO members in regard to “like” products.<sup>119</sup> For example, if a country offers a lower customs tariff on cigarettes for one country, this lower tariff must be applied to cigarettes from any other WTO member. WTO members thus cannot unjustifiably discriminate among their trading partners.

The general principle of “national treatment” prohibits discrimination in taxes and regulations between domestic and foreign (imported) goods.<sup>120</sup> A country may, for example, restrict pesticide use on fruit because of the risk to health. However, if that country applied the pesticide regulation to imported fruit but not domestic fruit, the policy would

violate the national treatment principle because the risk to consumers is the same irrespective of the fruit's country of origin.

The WTO Appellate Body (see box 15) has made it clear that health concerns are relevant in interpreting and applying the basic principles of international trade. In the *EC-Canada Asbestos Case* (2001), it upheld a French regulation prohibiting the manufacture, domestic sale, and import of asbestos-containing products. The Appellate Body stressed that human health is "important to the highest degree" and noted the strong scientific evidence that asbestos fibers were toxic, whereas similar fibers were not. Based on this distinction, they held that products containing asbestos were not "like" similar products containing other fibers and could properly be excluded.<sup>121</sup>

*National Health Regulation: Necessity  
and Less Trade-Restrictive Alternatives*

The drafters of the GATT were concerned that the nondiscrimination principles could interfere with states' sovereign rights to protect the health and safety of their citizens. Article XX(b) of the GATT states that nothing in the agreement shall be construed to prevent members from adopting and enforcing measures "necessary to protect human, animal or plant life or health."<sup>122</sup> Although countries have sovereignty to protect the health and safety of their populations, they cannot arbitrarily or unjustifiably discriminate between countries where the same conditions prevail or adopt measures as a subterfuge for discrimination.

The WTO often grants countries deference in determining the necessity of a public health regulation.<sup>123</sup> The Dispute Settlement Body panel does not inquire as to the necessity of underlying public health goals.<sup>124</sup> Thus, national health officials may set health policy goals. However, international trade law does review the means by which countries achieve health goals. The means must be science-based, although countries can rely on minority opinions that nonetheless represent a respected scientific authority.<sup>125</sup>

Despite the deference afforded to member states, the WTO will examine "reasonably available" alternatives in evaluating the necessity of a trade-restrictive health measure: "Import restrictions . . . [are] considered to be 'necessary' . . . only if there were no alternative measure consistent with the General Agreement . . . [which a country] could reasonably be expected to employ to achieve its health policy objectives."<sup>126</sup> In

the *Thailand-Cigarette Case*, decided under the health exception to the GATT 1947, the United States challenged Thailand's decision to ban the importation of cigarettes while permitting the sale of domestic cigarettes. Thailand argued that U.S. cigarettes contain chemicals and other additives that make them more harmful than Thai cigarettes, a claim affirmed by the WHO. The GATT dispute panel, however, found that Thailand's import ban was unnecessary because less trade-restrictive alternatives existed—e.g., warning labels, ingredient lists, and bans on certain additives. The panel did uphold Thailand's internal cigarette taxes and the ban on advertising and point-of-sale promotion.

### *Sanitary and Phytosanitary Measures (SPS)*

The SPS Agreement covers sanitary and phytosanitary measures, which are defined to include any measure applied to protect human life or health from “risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs” or “arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests” (Annex A, paragraphs 1[b])–[c]). The SPS Agreement affords members the sovereign right to protect the life and health of their human, animal, and plant populations, provided that such measures are “based on scientific principles” and do not constitute arbitrary, unjustifiable discrimination or a disguised restriction on international trade (Preamble, Art. 2[1]). National health measures that conform to the SPS Agreement are deemed to fulfill the country's obligations under the umbrella WTO agreement and specifically the GATT 1994 (Art. XX) (SPS, Art. 2[4]).

**International Standards.** The SPS Agreement reflects a preference for the adoption and use of international SPS standards to harmonize national measures. Members that adopt measures in conformity with such standards are automatically presumed to be in compliance with the SPS Agreement. In the area of food safety, the SPS Agreement explicitly recognizes the international standards developed by the joint FAO/WHO Codex Alimentarius Commission.<sup>127</sup> Thus, if a government bases its regulation (such as a maximum residue level for a pesticide in food) on Codex, it is presumed to meet WTO obligations. Members retain the sovereign authority to choose measures that result in a higher level of protection than would be achieved under international standards (Art. 3.3). A member choosing a stricter standard will, if challenged, have to demonstrate that

there is scientific support for its position and that it has conducted a risk assessment (Art. 5).

**Necessity and Science.** National SPS measures can be applied only to the extent necessary to protect human, animal, or plant life or health. They must be based on scientific principles and maintained only while justified by science (Art. 2[2]). There must be an “objective” or “rational” relationship between the SPS measure and the scientific evidence.<sup>128</sup>

**Risk Assessments.** National SPS measures must be based on objective risk assessments. Risk assessments must take into account available scientific evidence and public health methods, as well as economic costs. As explained in chapter 2, public health decisions often must be made under conditions of scientific uncertainty, and some argue for the application of the precautionary principle. The SPS Agreement permits the adoption of provisional measures based on the available data. Provisional measures, for example, could be taken in response to a novel outbreak of foodborne disease. Where this provision is invoked, members are required to seek the additional data needed to make a valid risk assessment, and while such investigations are pending, they must periodically review sanitary measures (Art. 5.7).

*The European Community Beef Hormone Case* (1998) examined the concepts of international standards, necessity, and risk assessments in the SPS Agreement.<sup>129</sup> The European Community (EC), in response to consumer concerns, banned imports of beef from cattle treated with one of six growth hormones. Five of these six hormones were governed by applicable international standards (Codex), but the EC argued that the import ban was permitted as a more stringent SPS measure designed to avert health risks. The risk assessment, however, failed to show that the hormones posed a significant risk to humans. The import ban violated the SPS Agreement because the EC did not conduct a risk assessment.<sup>130</sup>

*The European Community Biotech Products Case*, currently before the WTO, similarly concerns the adequacy of scientific data to support domestic health measures.<sup>131</sup> Despite the absence of scientific evidence that genetically modified (GM) food is harmful to humans,<sup>132</sup> European consumers sought the right to make informed choices. EU regulations require labeling and traceability, as well as authorization for placing GM ingredients on the market.<sup>133</sup> In 1999, the EU issued a four-year ban on new genetically modified crops. This resulted in three complaints to the WTO (from the United States, Canada, and Argentina). These cases were

consolidated, and in 2006 an expert panel of the WTO Dispute Settlement Body held that the EU moratorium on genetically modified organisms violated the SPS Agreement and the Agreement on Technical Barriers to Trade. The panel found insufficient scientific evidence to support the moratorium.<sup>134</sup> The EU plans to appeal this ruling to an Appellate Body set up by the WTO Dispute Settlement Body.

The GMO case is fascinating because it raises the question of whether the EU moratorium could be justified under the precautionary principle. The EU cited consumer apprehension about food safety, eroded public trust in government oversight of the food industry, and concern about environmental effects, particularly biodiversity. Consumers are often unwilling to consider science to be a guarantee of quality. Should countries be permitted to require strict labeling and traceability, or restrict sale of GM products, despite the trade-restrictive effects? Does human health require the right to know about potential risks to people or the environment?

The *Beef Hormone* and *Biotech Products* cases raise the question of why states must base their regulations on demonstrable health effects. Should the precautionary principle apply, so that industry carries the burden of proving that their products do *not* cause harmful effects? Should governments be permitted to consider “nonhealth” interests, such as potential effects on the ecosystem or even consumer preferences? Suppose the EU had simply required manufacturers to label their products as containing GM organisms; the outcome could be just as “trade-restrictive” because consumers might not buy the product. How should the trade system deal with consumer preferences and the “right to know”?<sup>135</sup>

### *Trade-Related Aspects of Intellectual Property Rights (TRIPS): Compulsory Licensing*

The TRIPS Agreement introduced intellectual property (IP) rules into the multilateral trading system. Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines, vaccines, and other high technology products lies in the invention, innovation, research, design, and testing. The TRIPS Agreement establishes minimum levels of IP protection that each WTO member must afford to creators, thus assuring more uniformity and bringing national policies under international rules with a dispute settlement system.

The central mission of the TRIPS Agreement is to protect and enforce IP rights “to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of pro-



ducers and users of technological knowledge and in a manner conducive to social and economic welfare” (Art. 7). Whether the TRIPS Agreement is fair and effective, however, is still subject to bitter dispute and ongoing negotiation.<sup>136</sup>

Affording IP protection gives creators incentives to generate ideas to benefit society as a whole. At the same time, by giving creators exclusive rights to their inventions, designs, or other ideas, IP protection can make products unaffordable. It is for this reason that IP rights are so politically charged.<sup>137</sup> To entrepreneurs, IP protection is indispensable to scientific innovation and the long-term public good. They argue that exclusive rights to a drug or vaccine are necessary to recoup the high costs of research and development. To consumer advocates, however, IP protection can make essential medicines so expensive as to be inaccessible to the world’s poorest people. Certainly, access to essential medicines is affected by many economic and noneconomic factors beyond IP protection. However, advocates believe that it is intolerable when countless people die of treatable diseases while pharmaceutical and biotech companies are enriched.

The TRIPS Agreement, in particular, has stirred intense debate about its effects on developing countries.<sup>138</sup> Arguably, poor countries do not have the systems of education, manufacturing, and marketing to innovate and gain the benefits of IP protection.<sup>139</sup> To these nations, TRIPS may afford little advantage because they possess few, if any, patentable products. At the same time, the TRIPS Agreement can make it difficult to produce or purchase affordable generic medications that countries need desperately. Some economists estimate that a transfer of \$60 billion per year from poor to rich countries would occur if the TRIPS Agreement were fully implemented—caused mainly by increased patent and royalty payments as well as higher prices.<sup>140</sup>

The TRIPS Agreement affords protection to a variety of IP rights, including trademarks, copyrights, and designs.<sup>141</sup> Patent protection is perhaps most important in matters of health. The agreement requires patents for inventions to last at least twenty years (Art. 33). Patent protection must be available for both products (e.g., medicines) and processes (e.g., methods of producing chemical ingredients for medicines) in almost all fields of technology, with certain exceptions (Art. 27).<sup>142</sup> The agreement allows countries to adopt measures necessary to protect the public’s health, provided that they are consistent with the provisions of the agreement (Art. 8).

The TRIPS Agreement allows countries to issue a compulsory license:

a legal vehicle whereby a government grants to itself or to a third party the right to produce or import a patented product without authorization from the patent holder (Art. 31). Compulsory licenses are subject to conditions: (1) the government must first attempt to negotiate a voluntary license from the right-holder on reasonable commercial terms; (2) the government need not seek a voluntary license in a national emergency or other urgent circumstance; (3) adequate remuneration must be paid to the right-holder, taking into account the economic value, if a compulsory license is issued; and (4) the compulsory license must be “predominantly for the supply of the domestic market.”

In the aftermath of TRIPS, many developing countries began resisting the restrictive concessions required by the agreement.<sup>143</sup> As a result, the international community gradually became more sensitive to the public health concerns of developing nations, lessening international support for the harsh intellectual property demands of the United States and other industrialized nations. Accordingly, the U.S. government adopted a new strategy of negotiating bilateral or regional agreements with individual countries in an attempt to implement a U.S.-type intellectual property regime that does not recognize the tension between public health and intellectual property.<sup>144</sup> These so-called TRIPS-plus agreements further undermine the ability of developing nations to protect the public health of their citizens, beyond the restrictive levels already achieved by the TRIPS Agreement.<sup>145</sup>

### *The Doha Declaration*

Although compulsory licensing was designed to provide the flexibility necessary to protect the public's health, the HIV/AIDS pandemic brought its shortcomings into stark contrast with its goals. Patented drugs cost anywhere from three to fifteen times that of their generic equivalents, although the cost of “front-line” drugs has been sharply reduced. Developing countries cannot afford to pay the high costs of combination drug therapy for HIV/AIDS—even when UNAIDS can negotiate a significantly lower cost. Highly active antiretroviral therapy reaches only 7 percent of people living with HIV/AIDS in low- and middle-income countries.

To ensure greater access to life-saving medications for resource-poor countries, the WTO Ministerial Conference promulgated the Declaration on the TRIPS Agreement and Public Health in November 2001.<sup>146</sup> The declaration explicitly recognized the public health problems facing resource-poor countries, especially HIV/AIDS, tuberculosis, and malaria. The declaration called for the TRIPS Agreement's “flexibilities” to be used

to protect the public's health by promoting access to essential medicines: Countries have the right to determine what constitutes a national emergency and the grounds on which compulsory licenses are granted.

Countries with manufacturing capacity, such as Brazil, India, and Thailand, can produce generic antiretroviral medications for their populations. Domestic production of generic drugs can yield dramatic health benefits. Brazil, for example, was able to reduce AIDS deaths by 50 percent over a four-year period.<sup>147</sup> Countries manufacturing generic drugs faced intense pressure from the United States and pharmaceutical companies to respect existing patents. Indeed, in 2001, thirty-nine drug companies sued the South African government to block the production of generic anti-HIV drugs on the grounds that it breached patent protection. The suit was dropped when the public and NGOs protested vehemently.<sup>148</sup>

The Doha Declaration left an important problem unresolved. It recognized that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." Industrialized countries could not help by exporting generic drugs because of the TRIPS Agreement requirement that compulsory licenses be primarily to supply the domestic market. The ministers charged the TRIPS Council to find "an expeditious solution to the problem" (Doha Declaration, paragraph 6).

A decision was nearly reached in December 2002, when 143 of 144 countries agreed to a waiver that would have allowed developed countries to export generic drugs made under compulsory license to countries that lacked manufacturing capacity. The United States was the only dissenter. Finally, in August 2003, all WTO members agreed to allow export of generic drugs under specified conditions.<sup>149</sup> Although the WHO has encouraged implementation of the August 2003 agreement,<sup>150</sup> progress has been painstakingly slow.<sup>151</sup>

The Doha Declaration was intended to prevent international trade rules from becoming a barrier to the provision of essential drugs.<sup>152</sup> Many problems remain, however, such as poor health care infrastructures in developing countries, making it difficult to deliver medicines to a large population and provide appropriate medical supervision. In retrospect, it is difficult to understand why politically and economically powerful countries would seek to use trade rules to prevent access to affordable treatments for the world's poor. It seems particularly incomprehensible that some members of the U.S. government argued for compulsory licensing of Ciprofloxacin Hydrochloride (Cipro) after the anthrax attacks in 2001

(which killed only a handful of people), while they opposed licensing of antiretrovirals for African nations burdened by millions of AIDS deaths.<sup>153</sup>

#### HUMAN RIGHTS: ADVANCING DIGNITY, JUSTICE, AND SECURITY IN HEALTH

Where after all do universal human rights begin? In small places, closest to home—so close and so small that they cannot be seen on any map of the world. Yet they are the world of the individual person: The neighborhood he lives in; the school or college he attends; the factory, farm or office where he works. Such are the places where every man, woman, and child seeks equal justice, equal opportunity, equal dignity without discrimination. Unless these rights have meaning there, they have little meaning anywhere. Without concerted citizen action to uphold them close to home, we shall look in vain for progress in the larger world.

Eleanor Roosevelt (1953)

International human rights law originated in response to the egregious affronts to peace and human dignity committed during World War II. The National Socialist German Workers Party (the Nazi Party of 1933–45) led by Adolf Hitler committed unspeakable atrocities, including genocide (Jews, the Roma, gays, people with disabilities) and human experimentation (sterilization, methods of execution, typhus, the effects of decompression and freezing water). The international community, after turning a blind eye to the events taking place during the Third Reich, was horrified when it realized the full extent of the wretchedness of the Nazi regime. Photographs of mass graves, piles of skeletons, and countless maltreated and emaciated prisoners were seared into the world's memory.

In the aftermath of the war, delegates of fifty nations signed the UN Charter at the San Francisco Conference on International Organization in 1945.<sup>154</sup> The U.S. representative, Eleanor Roosevelt, stressed the fundamental importance of human rights to a civilized world: "I know that we will be the sufferers if we let great wrongs occur without exerting ourselves to correct them."<sup>155</sup> In its preamble, the charter articulates the international community's determination "to reaffirm faith in fundamental human rights, [and] in the dignity and worth of the human person." The charter, as a binding treaty, pledges member states to promote "universal respect

**BOX 16****THE UNITED NATIONS HUMAN RIGHTS COUNCIL**

On March 15, 2005 the UN General Assembly voted to replace (effective June 2006) the Commission on Human Rights with the Human Rights Council. The council is a standing body with a generally elected membership, which meets no less than three times a year to address human rights concerns and evaluate the fulfillment of each UN member state's human rights obligations.

The council has been heralded as a bold move toward effective international protection for human rights and a significant improvement over the old commission, which met for one six-week session each year, and which suffered from a lack of credibility in recent years as it failed to adopt resolutions on the gross human rights violations in Iraq, Chechnya, and Darfur. The council gives any member the power to propose a country-specific resolution, and the frequency of meetings allows for faster action.

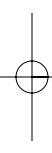
The old commission was frequently criticized for giving seats to member states with poor domestic human rights records, such as Zimbabwe, Libya, and Sudan; these states successfully thwarted action on their own human rights violations. The first set of member countries elected to the new council, however, has been controversial, and its actions have been criticized by human rights advocates. Six elected member states—China, Cuba, Pakistan, Russia, Saudi Arabia, and Azerbaijan—have been cited by human rights NGOs as not deserving membership. The United States (along with the Marshall Islands, Palau, and Israel) voted against the council's creation, claiming that it will have insufficient safeguards against membership of and control by rights-abusing nations; the United States did not seek a seat on the new council.

The General Assembly resolution establishing the council reaffirmed that "all human rights are universal, indivisible, interrelated, interdependent and mutually reinforcing and that all human rights must be treated in a fair and equal manner, on the same footing and with the same emphasis."<sup>1</sup> The resolution makes no mention of health but does reaffirm commitment to political, cultural, and socioeconomic rights, as well as the importance of development in the realization of human rights.

<sup>1</sup> G.A. Res. 60/521, U.N. Doc. A/60/L.48 (Mar. 15, 2006).

for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion" (Arts. 55, 56).

The charter established the Economic and Social Council (ECOSOC) as the principal organ to coordinate the economic and social work of the United Nations, notably international health and universal respect for human rights. ECOSOC created the Commission on Human Rights in 1946, and the Sub-Commission on Promotion and Protection of Human Rights the following year. (The Council on Human Rights replaced the Commission on Human Rights in 2005—see box 16.) The UN High Commissioner on Human Rights (UNHCHR), created in 1993, is the principal UN official with responsibility for human rights. The two international covenants created their own monitoring and compliance mechanisms: The International Covenant on Civil and Political Rights



<sup>a</sup> Based in Geneva.  
<sup>b</sup> Based in New York.  
<sup>c</sup> Based in Vienna.

Figure 29. United Nations human rights bodies.

(ICCPR) established the Human Rights Committee, and the International Covenant on Economic, Social, and Cultural Rights (ICESCR) established the Committee on Economic, Cultural and Social Rights (see figure 29).

The basic characteristics of human rights are that they inhere in all people because all people are human; they are universal, hence people everywhere in the world are “rights-holders”; and they impose robust duties on the state.<sup>156</sup> State duties, particularly applicable to economic, social, and cultural rights, encompass the obligation to *respect*—states do not interfere directly or indirectly with the enjoyment of human rights; *protect*—states take measures to prevent private actors from interfering with the right; and *fulfill* or *facilitate*—states take positive measures (e.g., legislative, budgetary, and promotional) to enable and assist individuals and communities to enjoy rights. Human rights are protected under international law, so that a state can no longer assert that systematic maltreatment of its own nationals is exclusively a domestic concern.<sup>157</sup>

The main source of human rights law within the UN system is the International Bill of Human Rights, comprising the UN Charter, the Universal Declaration of Human Rights, two international covenants on human rights, and an optional protocol. The United Nations has promulgated numerous treaties dealing with specific human rights violations, including racial and gender discrimination, the rights of the child, genocide, and torture.<sup>158</sup> Human rights are also protected under regional systems, including those in the Americas, Europe, and Africa.<sup>159</sup>

### *The Universal Declaration of Human Rights (UDHR)*

The UDHR, adopted in 1948, built upon the promise of the UN Charter by identifying specific rights and freedoms that deserve promotion and protection. The UDHR was the organized international community’s first attempt to establish “a common standard of achievement for all peoples and all nations” to promote human rights (Preamble). The UDHR represents a milestone in the struggle of humanity for freedom and human dignity, stating that human rights are self-evident, the “highest aspiration of the common people” (Preamble). Article 1 proclaims: “All human beings are born free and equal in dignity and rights.” The Universal Declaration is not a treaty but rather a resolution with no force of law. Nevertheless, its key provisions have so often been applied and accepted that they are now widely considered to have attained the status of customary international law.<sup>160</sup>

The adoption of the UDHR set the stage for a binding, treaty-based

scheme to promote and protect human rights. The ICCPR and the ICESCR were adopted in 1966 and entered into force in 1976.<sup>161</sup> The United States has ratified the ICCPR but not the ICESCR. The division of human rights into separate treaties perhaps symbolizes an ideological division between liberal democracies, which view personal autonomy and freedom as salient values, and countries with social welfare traditions, which view socioeconomic needs and equality as salient values. Although there are differences, it is important to emphasize that all rights are interdependent, interrelated, and of equal importance.

### *The ICCPR and the Optional Protocol*

The ICCPR imposes an immediate obligation “to respect and to ensure” civil and political rights (see table 10). The principal compliance mechanisms of the ICCPR are reporting and complaints systems.<sup>162</sup> States Parties are required to report to the Human Rights Committee (HRC), established by the ICCPR, on the measures adopted and progress made in the enjoyment of civil and political rights (Art. 40[1]). The ICCPR also empowers a State Party to charge another with a violation of the treaty, but the enforcement is weak (Arts. 42, 43). The interstate complaints system is available only if the state has acceded to the committee’s jurisdiction, and there is no formal adjudication procedure. Private parties may submit individual complaints, but only if the State Party has separately ratified the First Optional Protocol to the ICCPR. Individuals must first exhaust all available domestic remedies. The decisions or “views” of the HRC represent an important body of human rights case law. There is no specific enforcement, but the HRC has established a special rapporteur for follow-up and requires states to report their conformance measures.

### *The ICESCR*

The UDHR characterizes economic, social, and cultural rights as “indispensable for [a person’s] dignity and the development of his personality” (Art. 22) (see table 11). Yet, unlike the ICCPR, States Parties are not obliged to immediately implement the ICESCR but rather undertake:

to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized . . . by all appropriate means, including particularly the adoption of legislative measures. (Art. 2)



TABLE 10. International Covenant  
on Civil and Political Rights (ICCPR)

Nonderogable Rights <sup>a</sup>	Derogable Rights
Article 6: Freedom from arbitrary deprivation of life; inherent right to life	Articles 1, 25: Right to self-determination of the pursuit of economic, social, and cultural development
Article 7: Freedom from torture and cruel, inhuman, or degrading treatment or punishment and freedom from subjection without free consent to medical or scientific treatment	Article 9: Right to liberty and security of person; freedom from arbitrary arrest or detention
Article 8: Freedom from being held in slavery and servitude	Article 10: Right to be treated with humanity and with respect for the inherent dignity of the human person if deprived of liberty
Article 11: Freedom from imprisonment merely for an inability to fulfill contractual obligation	
Article 14: Right to be equal before courts and tribunals	
Article 15: Freedom from being convicted of an act that was not a criminal offense at the time of the action and freedom from imposition of heavier penalties than those imposed for the offense	Articles 17, 23: Freedom from arbitrary or unlawful interference with one's privacy, family, or reputation
Articles 16, 26: Right to recognition everywhere as a person before the law	Articles 21, 22: Right to peaceful assembly and association with others
Articles 18, 19: Freedom of thought, conscience, and religion	Article 24: Right of child to protection

NOTE: Adopted by General Assembly resolution 2200A (XXI) on December 16, 1966, entered into force March 23, 1976. The ICCPR supplements the Universal Declaration of Human Rights and enumerates fundamental civil and political rights that states must recognize and protect.

<sup>a</sup> Article 4, paragraph 2, lists seven nonderogable rights, rights that cannot be altered or suspended during public emergencies.

The language of “progressive realization” and “maximum resources” may have been inserted because economic and social rights typically require greater funding and more complex solutions than civil and political rights. Still, the Committee on Economic, Social and Cultural Rights, established by the ICESCR, made clear that States Parties do have immediate obligations. “Steps” toward the goal of full realization “must be taken within a reasonably short time.” States Parties have “a mini-

TABLE 11. International Covenant on Economic, Social and Cultural Rights (ICESCR)

Right <sup>a</sup>	Article
Right of self-determination to freely pursue economic, social, and cultural development	1
Right to work and to the opportunity to gain a living by freely chosen and accepted work	6
Right to the enjoyment of just and favorable conditions of work	7
Right to form and join trade unions of choice	8
Right to social security and social insurance	9
Protection of family, of mothers before and after childbirth, and of children from economic and social exploitation	10
Right to an adequate standard of living for self and family and to be free from hunger	11
Right to the enjoyment of the highest attainable standard of physical and mental health	12
Right to education	13
Right to take part in cultural life	15
Right to enjoy the benefits and applications of social progress	15
Right to benefit from the protection of moral or material interests resulting from one's own products	15

NOTE: Adopted by General Assembly resolution 2200A (XXI) on December 16, 1966, entered into force January 3, 1976. The ICESCR supplements the Universal Declaration of Human Rights and enumerates fundamental economic, social, and cultural rights that states should recognize and protect.

<sup>a</sup> The ICESCR does not recognize any rights as nonderogable. However, Article 4 specifies that these rights can only be limited by law, as long as the limitations are "compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society."

mun core obligation to ensure the satisfaction of . . . each of the rights." The committee also said that States Parties should immediately implement legislation and judicial remedies to ensure nondiscrimination in the exercise of economic and social rights (Art. 2[1]).<sup>163</sup>

The ICESCR does not establish a formal complaints system, but requires States Parties to submit reports to ECOSOC. The council has delegated the task of reviewing state reports to the Committee on Economic, Social and Cultural Rights.<sup>164</sup>

### *Valid Public Health Limitations on Human Rights*

Human rights have transcending value, but international law does allow restrictions when necessary for the public good. Under the UDHR, the

sole purpose for the limitation of rights is to secure “due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and general welfare in a democratic society (Art. 29[2]).” States may not “perform any act aimed at the destruction of any of the rights and freedoms” proclaimed in the declaration (Art. 30).

The two covenants diverge in their treatment of permissible derogations and limitations. The ICCPR’s most fundamental guarantees are so essential as to be absolute, and no state, even in a time of emergency, may derogate from them. The ICCPR, however, allows States Parties “in time of public emergency that threatens the life of the nation” to suspend most other civil and political rights (Art. 4) (see table 10). The state must officially proclaim the public emergency and cannot engage in discrimination. The principal conditions for restraints on civil and political rights are that they must be prescribed by law; be enacted within a democratic society; and be necessary to secure public order, public health, public morals, national security, public safety, or the rights and freedoms of others.<sup>165</sup> However, States Parties may not impose restrictions aimed at the destruction of rights or their limitation to a greater extent than provided in the covenant (Art. 5[1]).<sup>166</sup>

The Siracusa Principles, conceptualized at a meeting in Siracusa, Italy, in 1985, are widely recognized as a legal standard for measuring valid limitations on human rights.<sup>167</sup> The principles make clear that even when the state acts for good reasons, it must respect human dignity and freedom. Echoing the language of the ICCPR, the Siracusa Principles require that state limitations must be: in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable, or discriminatory. International tribunals have relied on the Siracusa Principles to require states to use the least restrictive measure necessary to achieve the public health purpose.<sup>168</sup>

It is far more difficult to think about legitimate limitations on economic, social, and cultural rights. The ICESCR permits “such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society (Art. 4).”<sup>169</sup> Since the ICESCR includes a “right to health,” it is best to conceptualize valid “limitations” as those measures necessary to attain health protection for the population. For example, the covenant requires States Parties to prevent, treat, and control epidemic, endemic, and occupational diseases

(Art. 12[2][c]). Thus, compulsory measures such as vaccination, treatment, or isolation would be permitted only if necessary to protect the public's health.

### *The "Right to Health"*

Human rights constitute perhaps the most important social movement of the twentieth century. In the latter part of that century and up to the present day, the theory and practice of human rights have been applied to another transcending human value: the health and safety of the world's population.<sup>170</sup> The International Bill of Human Rights, as well as numerous UN and regional human rights treaties, proclaims the right to health. Many countries also have incorporated a right to health or health care under domestic law<sup>171</sup> (see table 12).

The widespread recognition of health as an entitlement demonstrates its normative value in international law, even though states do not always safeguard the right to health. Viewing health as a fundamental right, part of the fabric of democracy and justice, transforms the social and political discourse.<sup>172</sup> The language of "rights" suggests that states have obligations and can be held accountable for violations.<sup>173</sup> The states' obligations, moreover, are not limited to medical care but extend to insurance of the socioeconomic conditions necessary for people to lead healthy and safe lives (e.g., nutrition, housing, uncontaminated drinking water, sanitation, safe workplaces, and a clean environment).

The basic mission of the United Nations includes the creation of conditions that support the world's health. The UN Charter pledges to find "solutions of international economic, social, [and] health problems" (Art. 56). Article 25 of the UDHR proclaims: "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control." Thus, the UDHR constructs the right to health as encompassing the basic necessities of life and a state-supported safety net of services.

The ICESCR recognizes "the right of everyone to the highest attainable standard of physical and mental health." Article 12 defines the steps needed to achieve full realization of the right to health: reduction of the stillbirth rate and infant mortality, and healthy development of the child; improvement in environmental and industrial hygiene; prevention,

TABLE 12. Sources for the human right to health

Document	Provision
<i>International Agreements</i>	
Universal Declaration on Human Rights	Everyone has a right to a standard of living adequate for the health and well-being of himself and of his family. (Art. 25)
International Covenant on Economic, Social and Cultural Rights	The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (Art. 12)
UN Declaration on the Rights of the Child	The child shall enjoy special protection, and shall be given opportunities and facilities . . . to enable him to develop physically, mentally, morally, spiritually and socially in a healthy and normal manner and in conditions of freedom and dignity. (Prin. 2)
Convention on the Elimination of All Forms of Discrimination against Women	States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning. (Art. 12)
Convention on the Elimination of All Forms of Racial Discrimination	States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee . . . the right to public health, medical care, social security and social services. (Art. 5)
<i>Regional Accords</i>	
European Social Charter	With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake . . . to remove as far as possible the causes of ill-health, to provide . . . facilities for the promotion of health and the encouragement of individual responsibility in matters of health, [and] to prevent as far as possible epidemic, endemic and other diseases. (Art. 11)
African Charter on Human and Peoples' Rights	Human beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right. (Art. 4)
American Convention on Human Rights: Protocol of San Salvador	Everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being. (Art. 10)

TABLE 12. (*continued*)

Document	Provision
<i>Major Initiatives</i>	
Declaration of Alma Ata	Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures. (Decl. V)
Vienna Declaration	The World Conference on Human Rights calls upon States to refrain from any unilateral measure . . . that creates obstacles to . . . the rights of everyone to a standard of living adequate for their health and well-being. (Decl. 31)
Rio Declaration on Environment and Development	Human beings are . . . entitled to a healthy and productive life in harmony with nature. (Prin. 1)
Copenhagen Declaration on Health Policy	We, the delegations of the Member States in the European Region of the World Health Organization, . . . pledge ourselves to promote and protect the health of our peoples as a fundamental value of our societies. (Opening)
Beijing Declaration	The explicit recognition and reaffirmation of the right of all women to control all aspects of their health, in particular their own fertility, is basic to their empowerment. (Decl. 17)
<i>National Constitutions</i>	
Constitution of South Africa	Everyone has the right to have access to health care services, including reproductive health care. (Bill of Rights, § 27(1))
Constitution of the Russian Federation	Everyone shall have the right to health care and medical assistance. (§ 1, Ch. 2, Art. 41)
Constitution of the Great Socialist People's Libyan Arab Jamahiriya	Health care is a right guaranteed by the State through the creation of hospitals and health establishments in accordance with the law. (Art. 15)
Constitution of the Republic of Haiti	The State has the absolute obligation to guarantee the right to life, health, and respect of the human person for all citizens without distinction, in conformity with the Universal Declaration of the Rights of Man. (Ch. 2, § A, Art. 19)
Constitution of the Republic of the Philippines	The State shall protect and promote the right to health of the people and instill health consciousness among them. (Art. II, § 15)

SOURCE: World Health Organization, "Twenty-five Questions and Answers on Health and Human Rights," *Health and Human Rights Publication Series*, 1 (2002): 29–31.

**BOX 17****THE RIGHT TO THE HIGHEST  
ATTAINABLE STANDARD OF HEALTH**

General Comment 14, issued by the Committee on Economic, Social and Cultural Rights (CESCR), proclaims that “health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.” The CESCR categorizes the right to health in terms of norms, obligations, violations, and implementation, and encourages states to “respect, protect, and fulfill” the right to health.

**Norms**

The normative content of the right to health is expressed in terms of “availability, accessibility, acceptability, and quality” of public health and health care services. “Availability” requires healthy conditions (e.g., safe and potable drinking water and sanitation) and functioning health services (e.g., hospitals, clinics, trained health care professionals, and essential drugs). “Accessibility” requires health services to be accessible to the entire population, without discrimination or physical, geographical, or economic barriers. “Acceptability” requires adherence to medical ethics and culturally appropriate health services. “Quality” requires health services to be scientifically and medically appropriate and of good quality.

**Obligations**

General Comment 14 imposes “core obligations” to ensure minimum services, including: (i) access to health on a nondiscriminatory basis, especially for vulnerable or marginalized groups; (ii) essential food that is nutritionally adequate and safe; (iii) basic shelter, sanitation, and safe and potable water; and (iv) essential drugs. The CESCR gives priority to the following services: reproductive and maternal, immunization, infectious disease control, and health information.

**Violations**

In determining which actions or omissions violate the right to health, it is important to distinguish between a state’s inability to comply (due to lack of resources) and its unwillingness to comply. Violations through *acts of omission* include failure to take appropriate steps to realize everyone’s right to the enjoyment of the highest attainable standard of physical and mental health. Violations through *actions* include state policies that contravene the standards set in the General Comment and are likely to result in injury, disease, or premature mortality (e.g., denial of access to health services or deliberate withholding of information vital to health).

**Implementation**

The General Comment contains detailed standards for implementing the right to health, including the duty to: (i) adopt framework legislation (e.g., a national strategy and plan of action, with sufficient resources); (ii) identify appropriate right to health indicators and benchmarks (e.g., to monitor improvements in community health); and (iii) establish adequate remedies and accountability (e.g., access to courts, ombudsmen, or human rights commissions).

**BOX 18****THE SPECIAL RAPPORTEUR  
ON THE RIGHT TO HEALTH**

The Commission on Human Rights created a Special Rapporteur on the Right to Health in 2002 with a mandate to form an understanding of “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>1</sup> The Rapporteur’s work includes gathering and sharing information, reporting on the status of the right to health, and proposing recommendations.

The first Special Rapporteur, Paul Hunt, was appointed in August 2002. He focused on themes relating to vulnerable populations: poverty, discrimination, and stigma.<sup>2</sup> He offered leading indicators (measures for evaluation) for the right to health: structures, processes, and outcomes. Structural indicators inquire whether adequate systems that affect health are in place (e.g., does the state include the right to health in its constitution?). Process and outcome indicators measure progress over time, consistent with the idea of the progressive realization (e.g., benchmarks or targets). Process indicators monitor effort (e.g., the proportion of women receiving prenatal care) and outcome indicators measure results (e.g., infant mortality and life expectancy).

The Special Rapporteur has issued reports on the elements of the right to health, reproductive rights, mental disabilities,<sup>3</sup> and the effects of trade on health.<sup>4</sup> By opening a dialogue between governments, civil society organizations, and international bodies, the Special Rapporteur has increased the visibility of the right to health while clarifying its meaning.

<sup>1</sup> UN Commission on Human Rights, Res. 2002/31, U.N. Doc. E/CN.4/2002/20 (Apr. 22, 2002).

<sup>2</sup> Hunt, U.N. Doc. E/CN.4/2005/51, ¶ 41.

<sup>3</sup> See also Lawrence O. Gostin and Lance Gable, “The Human Rights of Persons with Mental Disabilities: A Global Perspective on the Application of Human Rights Principles to Mental Health,” *Maryland Law Review*, 63 (2004): 120–21.

<sup>4</sup> Hunt, U.N. Doc. E/CN.4/2004/49.

treatment, and control of epidemic, endemic, and occupational diseases; and the creation of conditions to assure medical services in the event of sickness. The ICESCR, therefore, defines the right to health as encompassing both physical and mental health and offers concrete tasks to achieve the goal. The covenant refers to the “highest attainable” standard of health because many aspects of health are not within the state’s exclusive control—e.g., genetics, accidents, and socioeconomic class.

The meaning of the right to health is not inherent in the text. Work, therefore, is needed to clarify state obligations, identify violations, and establish criteria and procedures for enforcement. The contours of the right to health have been richly developed by the Committee on Economic, Social and Cultural Rights in General Comment No. 14<sup>174</sup> and by the Special Rapporteur on the Right to Health appointed by the General Assembly<sup>175</sup> (see boxes 17 and 18).

The International Bill of Human Rights has become a powerful tool



in public discourse and international law. Certainly, there are marked deficiencies in the clarity and enforcement of human rights. Nevertheless, a growing body of case law and commentary is advancing the theory and practice of international human rights. Just as important, the language of human rights is being employed in every region to assert fundamental claims of human dignity, inspire action, and persuade governments to act for the individual and collective good.

This chapter has explained the most basic problem in global health: why health hazards seem to change form and migrate everywhere on earth. States should care about serious health threats outside their borders and realize that solutions cannot be found solely in domestic regulation. Rather, the international community needs to find innovative ways to govern the wide variety of actors in the public and private sectors that powerfully influence global health. International law can play an important role in global needs for health protection. International instruments in a wide variety of health contexts have been created, but this chapter has only been able to discuss a few of the more important ones: the IHR, FCTC, WTO agreements, and international bill of human rights. This body of international law is certainly helpful, but much more needs to be accomplished to ensure adequate capacities to protect global health, as well as to foster greater cooperation among states and civil society more generally.

Amelioration of the enduring and complex problems of global health is virtually impossible without a collective response. No state or stakeholder, acting alone, can avert the ubiquitous threats of pathogens, and even unhealthy lifestyles, as they rapidly migrate. Truly effective global health governance could significantly improve life prospects for the world's population.

Given the pervasive health hazards faced by global society, perhaps we are coming to a tipping point where the status quo is no longer acceptable and it is time to take bold action. Global health, like global climate change, may soon become a matter so important to the world's future that it demands international attention, and no state can escape the responsibility to act.<sup>176</sup>